DOCTOR OF PHILOSOPHY

A Randomised Clinical Trial of the Effectiveness of Orthodontic Treatment between the 0.018-inch and the 0.022-inch Slot Conventional Ligation Bracket Systems

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A Randomised Clinical Trial of the Effectiveness of Orthodontic Treatment between the 0.018-inch and the 0.022-inch Slot Conventional Ligation Bracket Systems

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LIST OF ABBREVIATIONS

Abbreviation	Description
$\underline{1}$	Apicale $\underline{1}$
$\overline{1}$	Apicale $\overline{1}$
3D	Three Dimensional
ABO CR-EVAL	American Board of Orthodontics Cast-Radiograph Evaluation
ABO-DI	American Board of Orthodontics Discrepancy Index
ABO-OGS	American Board of Orthodontics Objective Grading System
AC	Aesthetic Component
AL	Anchorage Loss
ANOVA	Analysis of Variance Test
ANS	Anterior Nasal Spine
BOS	British Orthodontic Society
CBCT	Cone Beam Computed Tomography
CCA	Comprehensive Clinical Assessment
CCT	Controlled Clinical Trial
CHI	Community Health Index
Cl	Class
CONSORT	Consolidated Standard of Reporting Trials
CPQ	Child Perception Questionnaire
CVI	Content Validity Index
D1,2,3	Date 1,2,3
DAI	Dental Aesthetic Index
df	Degree of Freedom
DHC	Dental Health Component
DIDL	Dental Impact on Daily Living
Div	Division
GDP	General Dental Practitioner
Gn	Gnathion
Go	Gonion
ICC	Intraclass Correlation Coefficient
ICON	The Index of Complexity, Outcome, and Need
I-CVI	Item-Level Content Validity Index
ID	Identification
Ii	Incisor Inferius
IOTN	Index of Orthodontic Treatment Need
Is	Incisor Superius
L1-MP	Mandibular Incisor-Mandibular Plane
MBT	McLaughlin, Bennett, and Trevisi Bracket Prescription
Me	Menton
MIQ	Malocclusion Impact Questionnaire
mm	Millimetre
MP	Mandibular Plane
MPQ-SF	McGill Pain Questionnaire-Short Form
N	Number
NEO-FFI	NEO Five Factor Inventory

Abbreviation	Description
NHS	National Health Service
OASIS	Oral Aesthetic Subjective Impact Scale
OEQ	Orthodontic Experience Questionnaire
OH	Oral Hygiene
OHIP	Oral Health Impact Profile
OHIP-14	14-item Oral Health Impact Profile
OHQoL-UK	The United Kingdom Oral Health-Related Quality of Life
OHRQoL	Oral Health-Related Quality of Life
OIDP	Oral Impacts on Daily Performance
OIDP	Oral Impact on Daily Performance Questionnaire
OIIRR	Orthodontically-Induced Inflammatory Root Resorption
p	Porbability Value
PAR	Peer Assessment Rating
P-CPQ	Parental-Caregiver Perceptions Questionnaire
PIDAQ	Psychosocial Impact of Dental Aesthetics Questionnaire
PIL	Patient Information Leaflet
PNS	Posterior Nasal Spine
PP	Palatal Plane
P-P Plot	Probability/Probability Plot
R/L	Right/Left
RCT	Randomised Clinical Trial
S-CVI	Scale-Level Content Validity Index
S-CVI/Ave, S-CVI/UA	Scale-Level Content Validity Index/Average, Universal Agreement
SD	Standard Deviation
SE	Standard Error
SF-36	Short-Form 36-Item Health Survey
Sig.	Significance
SPPA	Self-Perception Profile for Adolescents
SPSS	Statistical Package for Social Sciences
ST-AI	State-Trait Anxiety Inventory
SWLS	Satisfaction with Life Scale
T0	Start of Treatment
T1	Nine Months from Treatment
TADs	Temporary Anchorage Devices
TCI	Treatment Complexity Index
TMJ	Temporo Mandibular Joint
U1-PP	Maxillary Incisor-Palatal Plane
UK	United Kingdom
US	United States of America
VAS	Visual Analogue Scale
Vs.	Versus
VIF	Variance Inflation Factor
VRS	Verbal Rating Scales
ZPRED/ZRESID	Plot of standardised predicted values (on the x axis) against the standardised residuals (on the y axis)

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DECLARATION

The candidate warrants he is the author of the thesis; that, unless otherwise stated, all references cited have been consulted by the candidate; that the work of which the thesis is a record has been done by the candidate and that it has not previously accepted for a higher degree.

Yassir Abdulkadhim Yassir Al-Naseri

Date: 28/9/2017

The supervisors warrant that the condition of the relevant Ordinance and Regulations of the University of Dundee for the degree of Doctor of Philosophy have been fulfilled.

Professor David Bearn

Date: 28/9/2017

Professor Grant McIntyre

Date: 28/9/2017

ABSTRACT

AIM: To compare the effectiveness of orthodontic treatment with the 0.018-inch and 0.022-inch slot conventional MBT bracket systems. The primary objective was to compare duration of treatment and the secondary objectives were to compare (1) quality of treatment outcomes as measured by the American Board of Orthodontics Cast-Radiograph Evaluation (ABO CR-EVAL), Peer Assessment Rating (PAR) scores, incisor inclination, anchorage loss, and patient perception; and (2) biological side effects of treatment as evaluated by the amount of maxillary central incisor root resorption after nine months from the start of treatment.

DESIGN: 2-arm parallel active group randomised clinical trial (RCT) with a 1:1 allocation ratio.

SETTING: Secondary care hospital environment in the National Health Service (NHS) Tayside in Scotland, United Kingdom.

SUBJECTS AND METHODS: Eligible patients aged 12 years or over were randomly allocated to treatment with either the 0.018-inch or 0.022-inch slot conventional MBT bracket systems (Victory series, 3M-Unitek, Monrovia, California). Randomisation was accomplished using a computer generated random code to a 10-number block of participants with allocation concealed in sequentially numbered, identical, opaque, and sealed envelopes. Outcome assessment was blinded. The treatment and archwire sequence were standardised and data were collected before, during and after treatment. Treatment outcome measures included: (1) duration of treatment (2) number of appointments and other treatment-related factors (3) ABO CR-EVAL (4) PAR scores and percentage PAR score reduction (5) incisor inclination, using cephalometric radiographs before and near end of treatment (6) anchorage loss (bilateral premolar extraction cases only), using 3D digital dental models with OrthoAnalyzer software

(3Shape, Copenhagen, Denmark) (7) patient perception using the aesthetic component of the Index of Orthodontic Treatment Need (IOTN AC) and three validated questionnaires before, during and after treatment and (8) central incisor root resorption using periapical radiographs before treatment and after nine months of treatment. Parametric tests (independent samples t-test and two-way ANOVA) and non-parametric tests (Chi-square with Fisher's exact tests, Mann-Whitney U test) were used to assess any differences between the groups. A multiple linear regression analysis was used to identify factors that influenced treatment duration for the total sample ($P < 0.05$).

RESULTS: One hundred and eighty-seven participants were randomised to treatment groups. Of those 34 participants withdrew or were excluded due to protocol deviations and poor cooperation. There were 77 patients in the 0.018-inch slot bracket group and 76 patients in the 0.022-inch slot bracket group (105 females and 48 males, overall mean age: 19.05 years). The baseline characteristics were similar between groups ($P > 0.05$). For the 0.018-inch and 0.022-inch groups: mean duration of treatment 29.26 and 31.17 months; median number of appointments 16 and 17; mean total ABO CR-EVAL score 34.71 and 34.49; mean percentage PAR score reduction 74.07% and 77.13%; mean change for maxillary incisor inclination 2.9˚ and 1.5˚ and for mandibular incisor inclination 2.7˚ and 1.4˚; mean anchorage loss (Left) 3.30 mm and 3.47 mm (Right) 3.86 mm and 3.73 mm, respectively. Incisor root resorption after nine months of treatment and improvement in patient perception of aesthetics after treatment were statistically significant with both groups ($P < 0.05$). However, there were no statistically significant differences between the two treatment groups in terms of treatment duration, number of appointments, ABO CR-EVAL, percentage PAR score reduction, incisor inclination, anchorage loss, patient perception of treatment, and incisor root resorption ($P > 0.05$). The regression analysis revealed that 33% of the variance in treatment duration could be explained by five variables: age at bonding, Class II division 2

malocclusion, number of failed appointments, number of emergency appointments, and greater than one clinician. No adverse events were observed during treatment.

CONCLUSIONS: There were no statistically or clinically significant differences in the duration of treatment, quality of occlusal outcomes, incisor torque delivery, patient perception or root resorption with either the 0.018-inch or 0.022-inch slot conventional MBT appliances. Increasing patient age, Class II division 2 malocclusion, number of failed and emergency appointments, and multi-operator treatment all increase the duration of orthodontic treatment.

CHAPTER 1: INTRODUCTION

The 0.018-inch and 0.022-inch slot size bracket systems were developed following metallurgical advances in archwire materials with each system having specific features, and differing benefits and drawbacks. Both systems continue to be widely used by clinicians worldwide with claims of clinical advantages and superiority of each system. However, to date, there is no robust scientific evidence to support orthodontic treatment with one slot size over the other, as all the available comparisons between the two slot sizes are of low quality. This leaves the choice of bracket slot size as subjective. There has been a long debate about the reason for the existence of two bracket slot size systems, with several orthodontists calling for one rather than two standards.

The current study was designed as a multicentre randomised clinical trial to compare the effectiveness of orthodontic treatment with the 0.018-inch and 0.022-inch slot size bracket systems.

In order to determine if one bracket slot size was more effective than the other, the main aspects of orthodontic treatment were investigated. These included:

- ***Duration of treatment:*** including the total duration of treatment, duration of the levelling and alignment stage, duration of the working and finishing stage and the number of appointments.
- ***Quality of treatment:*** this included quality of occlusal outcomes, incior inclination, anchorage loss, and patient perception of treatment (before, during, and after treatment).
- ***Biological side effects of treatment:*** the biological side effect of orthodontic treatment was represented by orthodontically-induced inflammatory root

resorption (OIIRR) affecting the maxillary central incisor teeth at nine months from the start of treatment.

The study also included two developmental studies that were carried out concurrently with the main randomised clinical trial:

- Three questionnaires to assess the perception of fixed appliance orthodontic therapy before, during and after treatment: validity and reliability

- Variation in bracket slot sizes and prescriptions used by specialist orthodontists in the United Kingdom (UK national survey)

Investigating these different aspects of treatment using a randomised clinical trial can reveal the potential superiority of one bracket slot size compared to the other. The clinical evidence provided by the current study can aid clinicians to use the most effective system accordingly.

CHAPTER 2: REVIEW OF LITERATURE

2.1 DURATION OF ORTHODONTIC TREATMENT

Orthodontic patients usually request treatment to improve their dental and facial appearance. Even if they are internally motivated and eager for treatment, they may become disappointed during treatment due to an unexpected long duration as well as physical and psychological impairments associated with the presence of the appliances. Therefore, treatment duration should be taken into consideration by the clinician and patient, since the success of the treatment and the satisfaction of patients depends on good cooperation.

Usually, the first concern of patients when they seek treatment is to find out how long treatment will take. For this reason, an accurate prediction of treatment time and the factors that might affect it are necessary to avoid any future complaints or premature termination of the treatment as well as to ensure high patient satisfaction and an accurate prediction of costs (Shia, 1986; Beckwith et al., 1999). The British Orthodontic Society advises that patients should be adequately informed about the proposed treatment and the expected timescale including the retention period, based on the specifics of each case (Jones, 1999).

A short duration of treatment has many advantages, such as reduced cost of treatment (Turbill et al., 2001), reduced potential harmful effects of the appliances on the teeth and oral tissues (Segal et al., 2004; Fox, 2005), and reduced negative impact on the psychological status and lifestyle of patients. From the orthodontist’s perspective, short treatment duration allows more patients with good compliance to be treated (Skidmore et al., 2006) and improving clinical efficiency as a result. Although a relatively long duration between orthodontic appointments can help in dissipation of the forces applied

to the teeth and allow peri-radicular regeneration and repair to take place, this can on the other hand reduce patient compliance (Roykó et al., 1999) and result in external apical root resorption (Segal et al., 2004; Pandis et al., 2008) and an increased risk of caries (Bishara and Ostby, 2008).

The duration of fixed appliance orthodontic treatment is generally around two years and is influenced by several factors. Different treatment modalities have been introduced to accelerate tooth movement and reduce the duration of treatment, such as low intensity laser therapy (Cruz et al., 2004; Yamaguchi et al., 2010), pulsed electromagnetic fields (Showkatbakhsh et al., 2010), electrical current (Kim et al., 2008), corticotomy (Hassan et al., 2010; Aboul-Ela, 2011), distraction osteogenesis (Işeri et al., 2005), and mechanical vibration (Nishimura et al., 2008). However due to hetrogeniety and small number of high quality studies, the systematic review by Long et al. (2013) concluded that the results about the effectiveness of these techniques on accelerating orthodontic tooth movement must be interpreted with caution.

In an attempt to investigate different factors influencing the duration of orthodontic treatment, Mavreas and Athanasiou (2008) conducted a systematic review. They included forty-one published studies from 1990 to the beginning of 2005 that were exclusively concerned with the duration of orthodontic treatment and various factors that might have an effect on this. The authors concluded that the duration of orthodontic treatment required future investigations to be accurately evaluated, as many of the studies that were included in their systematic review contained drawbacks and bias in their methodology or outcomes. Furthermore, they recommended future investigations are carried out on a prospective basis (Mavreas and Athanasiou, 2008).

2.1.1 Factors Influencing Duration of Orthodontic Treatment

Several studies have assessed the effect of various factors on treatment duration. This section gives an overview of these studies which will then be evaluated in detail in subsequent sections of this review. Some of these studies lacked sufficient information, such as the study by Shia (1986), who mentioned 18 factors that would increase treatment duration, although no data were provided. Vig et al. (1990) measured nine variables; five of them (the age at start of treatment, extraction or non-extraction, pre-treatment molar relationship, one or two arches treated, and the number of phases of treatment) had significant correlation with treatment duration, while no significant correlations were found with the other four variables. However, only 33% of the variance in the duration of treatment was explained in their study. Fink and Smith (1992) found that out of 18 variables measured, four factors were significantly associated with treatment duration (number of premolars extracted, number of missed appointments, pretreatment ANB, mandibular plane angles, and Salzmann Index). This explained only 24.9% of the variance in the duration of treatment. Beckwith et al. (1999) were able to explain 53.6% of the variation in orthodontic treatment duration using six of 31 variables some of which had not been investigated previously. This result is notable because it explained a higher percentage of variation when compared to previous studies and included a large number of variables. Interestingly, it can be noticed that three new variables were significantly associated with increased treatment duration (replacement of bands and brackets, oral hygiene level, and differences in orthodontic office attended) (Beckwith et al., 1999).

The study by Beckwith et al. (1999) showed some shortcomings, for instance, a small number of patients in certain groups and as a result, it could be argued that they were not thoroughly evaluated. Moreover, the study was inconclusive regarding the

relationship between bracket slot size and the duration of orthodontic treatment, because it was not intended to evaluate this as a primary objective. In spite of the association that was found between a shorter mean treatment duration and the 0.018-inch bracket slot, the authors indicated that this result could be a coincidental finding. Therefore, they suggested further investigations to specifically investigate the influence of slot size on the duration of treatment. The authors also recommended including more independent variables in order to be able to explain more variance in orthodontic treatment duration.

Turbill et al. (2001) conducted their retrospective study from the data of 1506 treated cases in England and Wales. They were able to explain 41% of the variance in orthodontic treatment duration, which was found to be positively correlated with factors related to the complexity of both malocclusion and the tooth movements, and with the thoroughness of the treatment approach. Although their sample size was adequate, more than half of the variance in treatment duration remained unexplained. The authors emphasised the importance of future prospective studies to evaluate other features that could not be included in their study. Furthermore, they highlighted the necessity for evaluating patient satisfaction throughout treatment due to its importance and variability in a way that might affect treatment duration i.e. whether patients are satisfied with a minor improvement or if they seek perfection.

Attempting to avoid the possible causes of bias, Haralabakis and Tsiliagkou (2004) designed their retrospective analysis using the data of 360 treated patients collected from the records of a private orthodontic office in Athens. They measured the inter-relationship of six variables on the duration of orthodontic treatment. Meanwhile, they excluded variables that might have introduced bias, such as cases with multiple treatment phases, impactions of teeth other than third molars, orthognathic surgery

cases, and patients with multiple missing appointments or broken appliances. Their final model could explain 46.33% of the variation in treatment duration and again a considerable percentage of variation without logical explanation. The authors suggested examining variables, such as tooth sizes and dental age as these may influence the rate of tooth movement and consequent treatment time. The authors also mentioned treatment difficulty as a possible cause of diversity. However, this is usually out of control of the clinician, whilst they minimised this source of heterogeneity by collecting data from the same clinician.

In 2006, Skidmore et al. published a study with several criteria comparable to that of Haralabakis and Tsiliagkou (2004). They conducted a retrospective analysis on 366 consecutively treated orthodontic patients by a single orthodontist and with a single phase of treatment in New Zealand. Thirty-eight percent of variation in treatment duration was explained by nine of the original 34 variables. The authors thought that the unexplained percentage might be due to three unexamined variables, namely; quality of finishing and time required for detailing the cases, patient satisfaction, and the adequacy of the diagnosis and treatment plan (Skidmore et al., 2006).

A retrospective study by Ang and Umesan (2011) found that a cumulative effect of several factors, such as the increased number of non-optimal intervals, adjustment or repair visits as well as a high percentage of extraction cases and a younger age at the start of treatment might be associated with a longer duration of orthodontic treatment. Like other retrospective studies, it would be difficult to ensure the accuracy of detailing every record and there is a possibility of missing data that could affect the results.

From the previous investigations, factors that affect the duration of orthodontic treatment can be categorised into the following (El-Angbawi, 2013):

1. ***Patient-related factors:***
    - Socio-demographic factors;
    - Characteristics of malocclusion; and
    - Patient cooperation.
2. ***Treatment-related factors:***
    - Extraction vs. non-extraction;
    - Phases of treatment;
    - Scheduled appointment intervals; and
    - Type of orthodontic appliance.
3. ***Operator and health care setting factors.***

2.1.1.1 Patient-Related Factors

2.1.1.1.1 Socio-Demographic Factors

2.1.1.1.1.1 Chronological Age

There is a general thought that orthodontic treatment is faster and simpler in younger patients when compared to adults. This could be a reflection of the fact that the supporting tissues of adolescents are in a state of proliferation with an extensive blood supply, whereas the supporting tissues of adults are in a state of rest with lower vascularity and cell proliferation and denser alveolar bone (Reitan, 1954). However, it should be taken into consideration that younger patients sometimes require more than one phase of treatment, such as removable or functional appliance followed by fixed appliances. Or else, fixed appliance treatment starts in the mixed dentition period which delays the progression of treatment until complete eruption takes place. On the other hand, mature patients often cooperate better with treatment and consequently the treatment duration of adults can be shortened (Popowich et al., 2005).

Studies that have investigated the effect of chronological age on the duration of treatment have shown controversial results. The studies by Dyer et al. (1991) and Robb et al. (1998) investigated primarily the effect of age at the start of treatment on the duration of orthodontic treatment. Both studies could not find a significant effect of age differences (adolescent and adult patients) on the duration of treatment. This was in spite of the differences between these two studies regarding selection criteria, for instance patients in Dyer et al. (1991) study were only females with Class II molar relationship and Class II division 1 incisors, while patients in Robb et al. (1998) study were males and females with majority of Class I malocclusion and treated with four premolar extractions. Table 1 summarises these studies.

Table 1: Summary of studies that have investigated the influence of chronological age (as a primary outcome) on orthodontic treatment duration

Study	Dyer et al.	Robb et al.
Study design	Retrospective	Retrospective
Year	1991	1998
Sample	56	72
Mean age (years)	Adolescents: 12.52 Adults: 27.57	Adolescent: 12.9 Adults: 31.3
Gender	Females	Males and females
Type of malocclusion	Class II	Class I: 94% Class II: 6%
Mean treatment duration (months)	Adolescents: 29.52 Adults: 30.72	Adolescents: 29.4 Adults: 30.6
Outcome	No statistically significant effect of age on treatment duration	No statistically significant effect of age on treatment duration

There are other studies that aimed to determine the factors influencing the duration of orthodontic treatment including age at the start of treatment. Table 2 summarises these studies. Fink and Smith (1992) investigated 118 patients with an age range from 8 years 5 months to 50 years 11 months and when used a regression analysis they found no significant contribution of age on the duration of treatment. This was the same finding from the study reported by Skidmore et al. in 2006. Beckwith et al. (1999) mentioned

that adults were treated faster than non-adults, but the chronological age of the child or adolescent patient did not significantly influence treatment duration (which agrees with the findings of Fink and Smith). However, Beckwith and his colleagues only reported the mean age of the children (12.2 years) without reporting that of adults. Moreover, the number of adult patients was only 16, while children were 124 in number. This could bias the results, as an insufficient number of adults were included.

Vig et al. (1990) found a significantly shorter treatment duration as the age of patient increased. They included a wide age range (7-53.1 years), but their results might be confused by the presence of confounding variables. Similarly, Firestone et al. (1999a) and Popowich et al. (2005) found that younger age was one of the predictors for an increased duration of treatment, especially when treatment started in the early mixed dentition period because this added extra treatment time whilst waiting for the complete eruption of the permanent teeth. Ang and Umesan (2011) reported in their study a weak but significant negative correlation between age and the duration of treatment. Nevertheless, they recommended further studies to investigate this conflicting correlation.

On the contrary, Turbill et al. (2001) reported that the mean duration of treatment for patients starting below 11 years of age (8 months) was significantly shorter than that for patients between 11-16 years of age (14.7 months). The authors attributed this to the simplicity of interceptive measures for patients below 11 years compared to more definitive treatment for patients above 11 years. No significant difference was found between the 11-16 and 16 years and above groups and since the percentage of patients who were aged 16 years and above was only 6.2% this comparison should be interpreted with caution due to the presence of selection bias.

2.1.1.1.1.2 Dental Age

The study by von Bremen and Pancherz (2002) assessed the efficiency of treatment (shorter treatment time with better outcomes) for patients with Class II division 1 malocclusion in three dental stages; early mixed dentition, late mixed dentition, and in the permanent dentition. The average duration of treatment was 37 months and the study concluded that the duration of treatment decreased as the dental age increased (early mixed dentition: 57 months; late mixed dentition: 33 months; permanent dentition: 21 months). An important finding of this study was that as the dental age progressed, the possibility of using two-phase approach of treatment decreased (such as functional/fixed appliances) and consequently the duration of treatment reduced.

Teh et al. (2000), Popowich et al. (2005), and Hsieh et al. (2005) all reported a longer duration of treatment when started earlier in the mixed dentition. Fisher et al. (2010) mentioned that the presence of deciduous teeth was more significantly associated with an increase in treatment duration when compared to chronological age. These results could also be explained by the presence of confounding factors, such as the possibility of a two-phase treatment approach or waiting for the full eruption of the permanent teeth to complete the treatment which in turn elongates the treatment duration.

In their systematic review, Mavreas and Athanasiou (2008) were less concerned about the importance of age differences on the duration of treatment as long as patients were treated in the permanent dentition stage.

Until an adequately designed study investigates the effect of age on the duration of treatment, the question will remain unanswered.

Table 2: Summary of studies that have investigated the influence of chronological age (as a secondary outcome) on orthodontic treatment duration

Study	Vig et al.	Fink and Smith	Beckwith et al.	Firestone et al.	Turbill et al.	Popowich et al.	Skidmore et al.	Ang and Umesan
Study design	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective
Year	1990	1992	1999	1999a	2001	2005	2006	2011
Sample	438	118	140	232	1506	237	366	100
Mean age (years)	13.3 (median)	18.18	Children: 12.2 Adults: Not reported	Group 1: 11.9 Group 2: 12.6	12.69	Cl I: 13.25 Cl II: 12.4 and 12.57	10.4-19.9	18.09
Gender	Males and females	Males and females	Males and females	Males and females	Not reported	Males and females	Males and females	Not reported
Type of malocclusion	Mixed	Mixed	Mixed	Mixed	Mixed	Cl I and Cl II	Mixed	Mixed
Mean treatment duration (months)	31.2-31.3	23.1	28.6	Not reported	13.1 (Geometric mean)	Cl I: 20.25 Cl II: 24.97-25.7	23.5	29.28
Outcome	Statistically significant decrease in treatment duration with increase in age	No statistically significant effect of age on treatment duration	Adults treated faster than non-adults. No statistically significant effect of children and adolescents age on treatment duration	Statistically significant decrease in treatment duration with increase in age	Statistically significant decrease in treatment duration for patients below 11 years	Statistically significant decrease in treatment duration with increase in age	No statistically significant effect of age on treatment duration	Statistically significant weak negative correlation between age and treatment duration

2.1.1.1.1.3 Gender

Gender is one of the confounding factors that may influence treatment duration. However, it is difficult to determine the actual effect of gender on treatment duration from the few studies that have been published to date. Two studies have found that males have significantly longer treatment duration. The Al Yami et al. (1998) retrospective study included 1870 patients (799 males and 1071 females) with a mean age of 13 ± 4.1 years who were treated in a university hospital. The authors noted that the mean treatment duration was 3.0 ± 1.4 years with statistically significant longer treatment duration for males (3.2 ± 1.5 years) than for females (2.9 ± 1.3 years). Skidmore et al. (2006) reported gender as one of the nine variables that were found to significantly influence treatment duration in their retrospective study of 366 patients (146 males and 220 females) with an age range 10.4-19.9 years (mean age: males 13.9 ± 1.3; females 13.6 ± 1.4) who were treated by one orthodontist. The mean treatment duration was 23.5 months and it was statistically significantly longer for males (24.3 months) than for females (23.1 months).

Although the Skidmore et al. (2006) study was carried out on a smaller sample than the Al Yami et al. (1998) study, a single clinician was used to treat the patients to reduce the effect of operator heterogeneity and this may explain the smaller difference in treatment duration found in the study by Skidmore et al. (2006). Vu et al. (2008) reported that the average treatment duration for males was 1.3 months longer than for females. However, this finding was not statistically significant. Other studies (Vig et al., 1990; Fink and Smith, 1992; O'Brien et al., 1995; Beckwith et al., 1999; Haralabakis and Tsiliagkou, 2004; Popowich et al., 2005) did not find a significant contribution of gender on the duration of treatment. On the contrary, Taylor et al. (1996) found that females required three months longer for the completion of treatment compared to males. As a consequence, the differences that have been found among studies may be

due to confounding from other variables, such as patient cooperation or a desire for a higher standard of finish. This might necessitate further investigation to specifically investigate the contribution of gender to the overall duration of treatment.

2.1.1.1.1.4 Ethnicity and Socioeconomic Status

Neither ethnicity (Parrish et al., 2011) nor the socioeconomic/socio-demographic status of orthodontic patients or their parents (Turbill et al., 2001; Turbill et al., 2003; Fisher et al., 2010) have been found to influence treatment time significantly. However, Turbill et al. (2003) stated that "lower social class may be a risk factor for discontinuation of orthodontic treatment, but not a predictor for it" (Turbill et al., 2003: 175).

2.1.1.1.1.5 Biological Variation

The rate of tooth movement can be influenced by a wide variation of individual biological responses to forces (Owman-Moll et al., 1996a). In an animal study, it was concluded that the individual characteristics was the determinant factor for the rate of bodily tooth movement but not the magnitude of force (Pilon et al., 1996).

2.1.1.1.2 Characteristics of Malocclusion

2.1.1.1.2.1 Type of Malocclusion

2.1.1.1.2.1.1 Dental malocclusion

Generally, it is thought that patients with Class II and Class III malocclusion require longer treatment than patients with a Class I malocclusion due to the greater range of tooth movement that is required. Studies that have investigated the effect of malocclusion type (according to Angle's classification) on treatment duration are summarised in Table 3.

From a stepwise regression analysis equation, the retrospective study by Vig et al. (1990) revealed that 4.5 months additional treatment time is required for cases with Class II division 2 malocclusion. This was supported later by Taylor et al. (1996).

Two retrospective studies in 1994 and a third in 1996 have been presented as congress abstracts to investigate the effect of malocclusion on treatment duration. Both Colella (1994) and Vig et al. (1994) used the same series of records from the University of Pittsburgh. Colella (1994) found that the mean duration of orthodontic treatment for Class II (28.71 months) was longer than that for Class I (24.66 months) by about four months. Vig et al. (1994) found that the duration of treatment of Class II malocclusion was lower with increased patient cooperation and orthodontist experience when compared to Class I malocclusion. Wenger et al. (1996) used records from the University of Pittsburgh and Ohio State and reported that the duration of treatment was the longest for Class II cases (29.9 ± 12.2 months) followed by Class III (28.2 ± 17.0 months) and the shortest for Class I cases (26.0 ± 13.4 months). These three studies support the finding of Vig et al. (1990) and were included in the systematic review by Mavreas and Athanasiou (2008). However, no further information exists about them. On close inspection, the mean values in the study by Wenger et al. (1996) showed a high degree of deviation, which might reflect a lack of accurate inclusion criteria and resultant selection bias influencing the results.

Amditis and Smith (2000) determined that the treatment of Class I malocclusion with both 0.018-inch and 0.022-inch slot bracket systems required less time on average when compared to both Class II and III malocclusions. However, their study did not specifically compare the different malocclusion groups but their primary objective was to compare the two bracket slot sizes.

Four retrospective studies by; Haralabakis and Tsiliagkou (2004), Popowich et al. (2005 and 2006) and Skidmore et al. (2006) all applied relatively strict selection criteria to reduce the possibility of bias. Haralabakis and Tsiliagkou (2004) found that Angle's Class II molar relationship was one of the variables that significantly increased treatment duration. Popowich et al. (2005 and 2006) combined data from three practices and discovered that Class II division 1 cases (extraction and non-extraction) took approximately five months longer than Class I non-extraction cases and this finding was similar to that by Vig et al. (1998). While the study by Skidmore et al. (2006) found that pre-treatment Class II molar relationship significantly contributed to an increase in treatment duration by 1.5 months on average (as determined by regression analysis), the mean treatment duration was not substantially different among the groups: Class I 21.9 ± 4.6 months, Class II 24.5 ± 4.5 months, and Class III 23.0 ± 5.3 months.

The retrospective study undertaken by Vu et al. (2008) to determine factors affecting orthodontic treatment duration showed that average orthodontic treatment duration was 29.0 ± 11.0 months. When divided according to Angle's classification this was Class I 26.08 ± 9.72 months, Class II 33.46 ± 11.65 months, and Class III 30.16 ± 9.29 months. This study indicated that Class I malocclusion cases were not only treated in a significantly shorter time (7.4 months) than Class II cases, but also with improved occlusal outcomes. Although Class III malocclusion required 4.1 months additional treatment time compared to Class I malocclusion, this was not statistically significant and could be due to greater variance and a small sample size for the Class III malocclusion group (only 25 patients of a total of 455 patients, comprising 5.5%). The study concluded that any deviation from Class I molar relationship would lengthen the treatment duration. This finding is in agreement with that of Robb et al. (1998) and Turbill et al. (2001) who reported that correction of anteroposterior buccal occlusion is one of the variables that could explain extended treatment duration. It is important to

mention that the results by Vu et al. (2008) should be interpreted with caution because of including both optimally finished and prematurely terminated (early debonded) cases and some of the cases had other complicating factors that could influence treatment time including the requirement for orthognathic surgery or being treated with a different approach e.g. the Tweed technique.

Beckwith et al. (1999) and Ang and Umesan (2011) could not find a significant association between molar malocclusion classification and treatment duration.

From the above studies, it can be seen that the general consensus indicates a significant increase in treatment duration for Class II malocclusion when compared to Class I malocclusion. Although the duration of treatment for Class III malocclusion in most studies has been found to be slightly longer than that for Class I malocclusion, it is shorter than treatment for cases with Class II malocclusion. This might be attributed to the fact that most studies have not included an adequate number of Class III cases in their sample, which in turn has highlighted the importance of an appropriate sample size to produce conclusive results. Design limitations are also present in previous studies since they were retrospective and no prospective study that has specifically investigated the effect of malocclusion on treatment duration.

2.1.1.1.2.1.2 Skeletal discrepancy

Skeletal morphology and discrepancies whether anteroposterior or vertical are usually measured from lateral cephalometric analyses. Some studies have included skeletal measurements to investigate if this influences treatment duration.

Fink and Smith (1992) reported that any anteroposterior discrepancy shown by an increase in the pre-treatment ANB angle will significantly increase treatment time, while for the vertical measurements they found that for each degree increase in the pre-

treatment mandibular plane angle, the treatment duration decreased by 0.3 months. However, the study could not find a similarly significant effect for the pre-treatment anterior facial height ratio as a predictor of treatment duration. Another retrospective study by Kim et al. (2000) evaluated 41 pre-treatment cephalometric variables as predictors of Class II treatment outcome and duration. They reported that 20% of the variance in treatment duration could be explained by skeletal, dental, and soft tissue variables. The anteroposterior skeletal measurements were; ANB angle, facial angle, and Wits appraisal, while the vertical measurements were; mandibular plane angle, Sn-Go-Gn angle, and ANS-Gn. Although these skeletal variables were considered as predictors of treatment duration in the study, they did not reach the level of significance.

A retrospective study by Popowich et al. (2005) for Class I (non-extraction) and Class II division 1 (extraction and non-extraction) patients agreed with the finding by Fink and Smith (1992) in that a larger pre-treatment ANB angle significantly contributed to an increase in treatment duration. But contrary to Fink and Smith (1992), they could not find any significant influence of the mandibular plane angle and other skeletal variables on treatment time. Paradoxically, Fisher et al. (2010) found that the only skeletal variable associated with longer treatment duration was the lower facial height, while other skeletal measurements, such as ANB angle were not significantly associated.

The comparison of studies investigating the relationship between skeletal measurements and duration of treatment was complicated due to the presence of a variety of skeletal measurements in these studies and the absence of a consensus of a single accepted method of analysis. From the available information, it appears that there is a tendency towards an increase in treatment duration when a case is skeletally Class II as measured by ANB angle.

Table 3: Summary of studies that have investigated the influence of dental malocclusion type on orthodontic treatment duration (continued next page)

Study	Vig et al.	Colella et al.	Vig et al.	Wenger et al.	Taylor et al.	Vig et al.	Beckwith et al.
Study design	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective
Year	1990	1994	1994	1996	1996	1998	1999
Sample	438	487	487	Not reported	81*	966	140
Age (mean or range/years)	13.3 (median)	11-14	11-14	Not reported	13.8	Not reported	Children: 12.2 Adults: Not reported
Gender	Males and females	Males and females	Males and females	Males and females	Males and females	Males and females	Males and females
Type of malocclusion	Mixed	Cl I and Cl II	Cl I and Cl II	Mixed	Mixed	Cl I and Cl II	Mixed
Distribution of malocclusion	Cl I: 43.7% Cl II: 50.8% Cl III: 5.5%	Cl I: 176 patients Cl II: 311 patients	Cl I: 176 patients Cl II: 311 patients	Not reported	Not reported	Cl I: 399 patients Cl II: 567 patients	Cl I: 35% Cl II: 55.7% Cl III: 9.3%
Outcome	Class II division 2 added 4.5 months to treatment duration	Longer duration of treatment for Class II malocclusion	Duration of treatment of Class II malocclusion was reduced by increasing patient cooperation and orthodontist experience	Longest duration of treatment for Class II malocclusion, followed by Class III and Class I, respectively	Class II division 2 was one of the factors that increased treatment duration	Class II division 1 took on average 5 months longer treatment duration than Class I malocclusion	No significant effect of molar classification on treatment duration

Study	Amditis and Smith	Haralabakis and Tsiliagkou	Popowich et al.	Skidmore et al.	Vu et al.	Ang and Umesan
Study design	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective
Year	2000	2004	2005 and 2006	2006	2008	2011
Sample	64	360	237	366	455	100
Age (mean or range/years)	0.018'': 15.6 0.022'': 14.9	17.0	Cl I: 13.25 Cl II: 12.4, 12.57	10.4-19.9	16.3	18.09
Gender	Males and females	Males and females	Males and females	Males and females	Males and females	Males and females
Type of malocclusion	Mixed	Mixed	Cl I and Cl II	Mixed	Mixed	Mixed
Distribution of malocclusion	Cl I: 45.3% Cl II: 37.5% Cl III: 17.2%	Not reported	Cl I: 77 patients Cl II: 160 patients	Cl I: 36.9% Cl II: 61.7% Cl III: 1.4%	Cl I: 57.4% Cl II: 37.1% Cl III: 5.5%	Cl I: 29 Cl II: 51 Cl III: 20
Outcome	Treatment of Class I malocclusion with both 0.018-inch and 0.022-inch slot bracket system required less mean duration compared with Class II and III	Molar relationship malocclusion was one of the variables that significantly increased treatment duration	Class II division 1 malocclusion took 5 months longer treatment duration than Class I non-extraction cases	Pre-treatment Class II molar relationship was significantly contributed to increasing treatment duration by 1.5 months	Class II malocclusion took 7.4 months longer treatment duration than Class I malocclusion	No significant association between malocclusion classification and treatment duration

*81 cases of fixed appliance from a total of 156 cases

2.1.1.1.2.2 Severity of Malocclusion

Janson et al. (2009) conducted a retrospective study to compare the efficiency of treatment for two groups of patients with Class II malocclusion divided according to severity (half unit Class II and full unit Class II malocclusion). The results showed that patients with half unit Class II malocclusion had a significantly shorter treatment duration (25.06 ± 9.92 months) than those with a full unit Class II malocclusion (31.20 ± 11.05 months) when treated without extractions. This study was designed so that both groups received a similar treatment protocol, though sample selection depended solely on an anteroposterior dental relationship regardless of any other dentoalveolar or skeletal features.

Canine impaction is one of the factors that is known to increase the complexity of orthodontic cases and consequently the treatment duration. A retrospective study by Stewart et al. (2001) revealed that unilaterally and bilaterally impacted canines added 3.4 and 9.9 months to treatment duration, respectively, when compared to a control group without impactions. The severity of impaction was found to be greater in bilateral impaction cases and this can explain the greater duration of treatment in the bilateral impaction group. On the other hand, Vu et al. (2008) investigated a larger sample but did not find a significant association between canine impaction and increased treatment time. The disagreement between these studies may be attributed to the difference in several factors, such as the position and complexity of canine impaction or the differences in the treatment technique (surgical exposure or ‘wait and see’). Fleming et al. (2009a) found that neither angulation nor the vertical height of the impacted canine could predict treatment duration, but the mesiodistal position of the impacted canine may be predictive. On the other hand, Bazargani et al. (2013) concluded that “on average” treatment duration could be increased by 1.2 months for every millimetre increase in distance of the palatally displaced canine from the occlusal plane. It is clear

that controversies are present between these retrospective studies and therefore a prospective RCT is required to limit the confounding variables and confirm the results.

A number of indices that aim to objectively assess the severity or complexity of malocclusion have been developed and widely used to evaluate the severity and effectiveness of orthodontic treatment. A summary of the studies that have correlated these indices with treatment duration is listed below.

Most studies that have investigated treatment duration and the severity of malocclusion using the PAR index (Peer Assessment Rating) have shown that an increased pre-treatment PAR score is associated with increased treatment duration (Table 4). However, some studies have not presented a clear interpretation of their results.

A retrospective study by Vu et al. (2008) reported that the American Board of Orthodontics Discrepancy Index (ABO-DI) (used to evaluate the severity of pre-treatment malocclusion) and the Treatment Complexity Index (TCI) (to evaluate the complexity of cases based on treatment modalities), were significantly associated with increased treatment duration. They considered these indices as sensitive prospective predictors of treatment duration. For every single point increase in the DI and the TCI, the treatment duration increased by 0.1 months and 2.3 months, respectively. Parrish et al. published their retrospective study in 2011 and considered it as the first study that primarily aimed to compare the ABO-DI and orthodontic treatment duration. Their sample was university clinical records of 732 patients treated in the permanent dentition. They showed that the average treatment duration was increased by 11 days for each point increase in total DI score. The total DI score explained 9% of the variability in treatment duration. In contrast to these studies, Djeu et al. (2005) and Jain et al. (2013) could not find a significant correlation between any of the ABO-DI categories and treatment duration.

Table 4: Summary of studies that have investigated the effect of severity of malocclusion using the PAR index on orthodontic treatment duration

Study	Study design	Year	Sample size	Type of malocclusion	PAR Weighting	Correlation between pre-treatment PAR and duration of treatment
O'Brien et al.	Retrospective	1995	250	Cl II div. 1	US	Positive significant association
Taylor et al.	Retrospective	1996	81*	Mixed	UK	Positive significant association
McGuinness and McDonald	Retrospective	1998	60	Mixed	UK	No association
Robb et al.	Retrospective	1998	72	Cl I and Cl II	US	Positive association but lack of predictive value
Firestone et al.	Retrospective	1999a	232	Mixed	UK	No association
Teh et al.	Retrospective	2000	128	Mixed	UK	Positive significant association
Dyken et al.	Retrospective	2001	105	Mixed	UK and US	Positive significant association
Turbill et al.	Retrospective	2001	1506	Mixed	UK	Smaller increase in duration especially for high combined right and left buccal occlusion PAR score
Mascarenhas and Vig	Retrospective	2002	308	Mixed	UK	Positive significant association
Cassinelli et al.	Retrospective	2003	200	Mixed	UK	Positive significant association
Haralabakis and Tsiliagkou	Retrospective	2004	360	Mixed	UK	Positive significant association
Popowich et al.	Retrospective	2006	237	Cl I and Cl II	US	No association
Machibya et al.	Retrospective	2013	69	Mixed	UK	Positive significant association
Leon-Salazar et al.	Retrospective	2014	111	Cl I	US	No association

*81 cases of fixed appliance from a total of 156 cases

The Salzmann index was used by Fink and Smith (1992) to measure the pre-treatment severity of orthodontic cases and they found by using stepwise multiple regression analyses that an increased pre-treatment Salzmann index score was significantly correlated with increased treatment duration. At the same time, the authors stated that this index was not sufficiently sensitive to measure the detailed finishing of cases, including factors such as root torque, angulation and detailed aspects of intercuspation.

No study has aimed primarily to correlate the Index of Orthodontic Treatment Need (IOTN) and treatment duration. Studies that have used this index as one of the factors that might influence treatment duration are neither conclusive nor in agreement, as some of them have found an association between the IOTN or one of its individual components with longer treatment duration (Teh et al., 2000; Turbill et al., 2001; Cassinelli et al., 2003), whereas others could not find such an association (Taylor et al., 1996; Firestone et al., 1999a). The reason behind this apparent confusion might be because this index was originally developed to measure the need for treatment and not the severity of the case and, as a result, the assessment of treatment need is not necessarily associated with treatment complexity or treatment duration.

Severity of malocclusion is different to complexity of treatment. Severity as measured with occlusal indices (e.g. PAR Index) is commonly malocclusion related, which may not be related to complexity, as the latter is influenced by variables beyond the malocclusion itself. These may be patient related, such as the agreed aim of treatment, growth potential, compliance, and general oral health, or clinician related including the level of expertise, quality of support services, and limited resources (Kirschen, 1997).

2.1.1.1.2.3 Quality of Occlusal Finish

Pinskaya et al. (2004) and Knierim et al. (2006) found a significant association between increased treatment duration and deterioration in treatment outcomes as measured by the ABO Cast-Radiograph Evaluation (ABO CR-EVAL) and the Comprehensive Clinical Assessment (CCA). Hsieh et al. (2005) found that longer treatment duration was only correlated with a worse outcome (CCA) when treatment started early (mixed dentition), but the ABO CR-EVAL did not detect such an association. In these studies, the results were mainly attributed to patient burnout and poor compliance. Consistent with these studies, Campbell et al. (2007) concluded that longer treatment duration was

associated with a higher chance of premature termination of treatment as well as poorer treatment results (ABO CR-EVAL and CCA). Also, Wes Fleming et al. (2008) mentioned that for patients whose treatment took longer, they had significantly worse treatment results (ABO CR-EVAL) and they indicated that every one point increase in the overall CR-EVAL was associated with an additional three months of treatment.

2.1.1.1.3 Patient Cooperation

Patient cooperation during orthodontic treatment has been explored in several studies along with the other factors that might influence treatment duration. However, Mavreas and Athanasiou (2008) did not include this in their systematic review. Studies have investigated patient cooperation in terms of missed scheduled appointments, breakage of appliance/debonded brackets and repair, cooperation in wearing elastics, and adequate oral hygiene throughout treatment (Table 5). These variables can be considered as good indicators for patient compliance.

Most of the studies that have investigated the relation between patient cooperation and treatment duration have found a positive relationship either directly or indirectly. Shia (1986) reported from his private practice that poor patient cooperation, broken appointments, and appliance breakages were the top three factors associated with long treatment duration, but he did not present any data to support these findings. O'Brien et al. (1995) found that broken appointments and appliance breakage/repairs had the greatest effect in their regression model. The same factors explained 46% of the variance in orthodontic treatment duration in the study by Robb et al. (1998) and 44% by Melo et al. (2013). Beckwith et al. (1999) found that three of the top four contributors that explained long treatment duration fell into the "patient cooperation" category. The study by Cassinelli et al. (2003) did not correlate treatment duration and patient compliance directly, but they found that difficult cases took longer to treat than

simpler cases and were more likely to be associated with problems relating to cooperation and oral hygiene. On the other hand, the study by Grewe and Hermanso (1973) could not identify a significant relationship between treatment duration and subjective assessment of patient cooperation. Another group of studies, such as that by Haralabakis and Tsiliagkou (2004) excluded patients who had more than two missed appointments and more than five broken, loose or lost appliances components; because they considered them as confounding variables that would introduce bias.

It can be argued that brackets and bands debonding/debanding might be the result of poor patient compliance or due to other confounding factors which are related to bonding/banding materials or operator skills/preferences (Beckwith et al., 1999). However, Skidmore et al. (2006) overcame this by distinguishing between brackets rebonded due to a clinical decision and brackets/bands replaced due to poor patient compliance. In spite of all the variation present in these retrospective studies in terms of inclusion criteria, data presentation, treatment technique and operator numbers, they have generally agreed that patient cooperation influences treatment duration. A well-designed prospective study is required to confirm this result.

Table 5: Summary of studies that have investigated the association between treatment duration and categorical factors of patient cooperation

Study	Year	Sample	Missed appointments	Appliance breakage/debond and repair	Elastics wear compliance	Oral hygiene
Shia	1986	500	Significant association with treatment duration (the second important factor after patient cooperation)	Significant association with treatment duration (the third important factor)	Not investigated	Not investigated
Fink and Smith	1992	118	Significant association (each missed appointment added 0.8 months to treatment duration)	Not investigated	Not investigated	Not investigated
O'Brien et al.	1995	250	Significant association with treatment duration	Significant association with treatment duration	Not investigated	Not investigated
Taylor et al.	1996	81	No significant association with treatment duration	No significant association with treatment duration	Not investigated	No significant association with treatment duration
Robb et al.	1998	72	Significant association and explained 30% of variance in treatment duration	Significant association and explained 16% of variance in treatment duration	Not investigated	Not investigated
Beckwith et al.	1999	140	Significant association (the first important factor) each missed appointment added 1.09 months to treatment duration and explained 17.6% of variance in treatment duration	Significant association (the second important factor) each replaced bracket and band added 2 weeks to treatment duration and explained 13% of variance in treatment duration	No significant association	Significant association. Poor oral hygiene associated with an increase of 0.67 months per chart entry and explained 5.6% of variance in treatment duration
Pinskaya et al.	2004	521	Significant association with treatment duration	Not investigated	Significant association with treatment duration	Poor compliance with OH was associated with long treatment duration
Popowich et al.	2005	237	No significant association with treatment duration for Class II patients	Significant association with treatment duration for Class II patients	Significant association with treatment duration for Class II patients	Not investigated
Knierim et al.	2006	437	Not investigated	Not investigated	Not investigated	Poor OH was significantly associated with long treatment duration

Study	Year	Sample	Missed appointments	Appliance breakage/debond and repair	Elastics wear compliance	Oral hygiene
Skidmore et al.	2006	366	Significant association (each missed appointment added 1.4 months; 2 or more missed appointments added 3 months to treatment duration)	Significant association (each debonded bracket added 0.3 months on average; 3 or more debonds added 1.5 months to treatment duration)	Significant association (1 or 2 poor elastic wear added 2.6 months; 3 or poorer elastic wear added 4.5 months to treatment duration)	Significant association (1 or 2 poor OH entry added 0.9 months; 3 or more poor OH entries added 2.2 months to treatment duration)
Vu et al.	2008	455	Significant association (less than 2 missed appointments decreased treatment duration by 7.2 months than in patients who missed 2 or more appointments)	Significant association with treatment duration	Not investigated	Significant association (no negative OH entries decreased treatment duration by 4.5 months than in poor OH)
Ang and Umesan	2011	100	Significant association with treatment duration	Significant association with treatment duration	Not investigated	Not investigated
Melo et al.	2013	70	Significant association and explained 14% of variance in treatment duration	Significant association and explained 29.7% of variance in treatment duration	Not investigated	Not investigated

All studies are retrospective. An increase in missed appointment, appliance breakage and repair, poor compliance in elastic wear and oral hygiene increased treatment time

2.1.1.2 Treatment-Related Factors

2.1.1.2.1 Extraction vs. Non-Extraction

The influence of extractions on treatment duration has been investigated from different aspects. Studies have either investigated this influence primarily or with other factors. Extraction pattern and the time of extraction have also been considered.

Vig et al. (1990), Popowich et al. (2005 and 2006) and Janson et al. (2007 and 2012) compared groups of patients with and without extraction. Vig et al. (1990) conducted a pilot study on records from five practices with very high (84%) or low (25%) extraction rates in Michigan to detect any relationship between the relative frequency of extractions and treatment duration. The result indicated that pooling all the data from five practices showed no significant differences in the mean duration of treatment between extraction (31.2 months) and non-extraction (31.3 months) cases. However, when comparing each practice individually, longer treatment duration was generally found for patients who had extractions but it was statistically significant in only one practice, which had the smallest number of non-extraction cases. Using stepwise multiple regression analyses, they found that 2.9 months were added to the treatment duration when this included extractions. This retrospective study did not provide conclusive results and the authors highlighted the presence of confounding variables, which might have biased the results.

Popowich et al. published two retrospective studies in 2005 and 2006 based on the same records. They reported that extractions did not significantly influence the duration of treatment and there was no significant difference in average treatment duration between Class II division 1 non-extraction (25.7 months) and Class II division 1 extraction (24.97 months) cases, however they found a significantly higher average number of appointments (1.7 greater) for the Class II non-extraction group than the Class II

extraction group. They related this difference to the use of more Class II appliances in the non-extraction group than in the extraction group and this required extra visits for the insertion and activation of these appliances. Although this difference is statistically significant, it may not be clinically important.

Janson et al. (2007) compared two groups of patients with Class II malocclusion who were treated with two maxillary premolar extractions and without extractions, where the initial malocclusion type and severity were similar. They found no statistically significant difference between the two groups regarding the mean treatment duration. However, they also reported that if premolar extraction was carried out immediately the treatment time was shorter. Janson et al. (2012) stated that the duration of treatment for cases with Class II division 1 requiring four premolar extractions and Class II division I non-extraction cases were similar (2.36 and 2.47 years, respectively) and the statistically non-significant difference of 0.11 years (1.3 months) was also considered not clinically relevant.

In order to exclude the confounding influence of the severity of malocclusion, three studies have been conducted on borderline cases that were treated with and without extractions to investigate the effect of extractions on treatment outcomes. Xu et al. (2006) used records of 39 Chinese patients who met specific selection criteria to identify the borderline cases, 16 patients had been treated without extraction and 23 had four first or second premolars extracted. The study revealed that the extraction cases had longer mean treatment duration (24.7 months) than the non-extraction cases (22.1 months), however, no statistical test was presented in the study to assess this difference. Another retrospective study was conducted by Lim et al. (2008) to detect the aesthetic impact of premolar extractions and non-extraction treatment from records of “borderline” Korean patients. This study did not report clearly the procedure for

identification of “borderline” cases as in the study by Xu et al. (2006), but they also found that the average treatment duration for extraction cases was longer than that for non-extraction cases (27.2 and 23.0 months, respectively). Again the authors did not compare or focuse on the difference in treatment duration in spite of their larger sample size (50 extraction cases and 50 non-extraction cases). The only prospective randomised study investigating the effect of extraction/non-extraction (air rotor stripping) on facial aesthetics in post-adolescent “borderline” Turkish patients was published by Germeç and Taner (2008). The study recruited only 26 patients with a borderline Angle Class I molar relationship and no skeletal discrepancy during a four-year period. The study concluded that the mean treatment duration was significantly longer for the extraction group (24.8 months) when compared to the non-extraction group (17.0 months), which might be due to the time required for space closure in extraction cases.

Some studies have been designed to investigate different factors influencing treatment duration. However, they have not been designed to detect the effect of extractions as a primary objective. The influence of extraction in these studies will be predented below. One of the aims of study by Taylor et al. (1996) was to identify factors associated with duration of removable and fixed orthodontic treatment. They divided their sample accordingly and analysed them separately. Multiple linear regression analysis for the 81 records of fixed appliance treatment did not include the extraction factor and the authors concluded that it was impossible to predict the duration of fixed appliance orthodontic treatment from their study material. The study by Beckwith et al. (1999) could not find any significant influence of extractions on treatment duration. Although the mean treatment duration for extraction cases (29.2 months) was longer than that for non-extraction cases by 1.4 months, this difference was not statistically significantly different. It should be noted that in this study the percentage of extraction cases was 24.3% while the non-extraction cases were 75.7%, which is likely to have introduced

bias to the results. In agreement with the above two investigations, Firestone et al. (1999a) and Melo et al. (2013) did not find a significant relationship between extraction and treatment duration. Conversely, other studies have found that extractions (and multiple extractions) have a significant influence on some of the variation of treatment duration among patients (Alger, 1988; Fink and Smith, 1992; O'Brien et al., 1995; Vig et al., 1998; Teh et al., 2000; Turbill et al., 2001; Mascarenhas and Vig, 2002; Haralabakis and Tsiliagkou, 2004; Pinskaya et al., 2004; Skidmore et al., 2006; Hamilton et al., 2008; Mavreas and Athanasiou, 2008; Vu et al., 2008; Fisher et al., 2010; Ang and Umesan, 2011; Leon-Salazar et al., 2014). In these studies extraction cases required on average between 0.9 months (Fink and Smith, 1992) and 9.1 months (Turbill et al., 2001) longer treatment duration when compared to non-extraction cases.

The extraction pattern in orthodontic treatment has also been investigated. Vu et al. (2008) found no significant difference in the duration of treatment based on the number and pattern of extractions, but there was a significant difference between whether the case had extractions or not. On the other hand, Alger (1988), Turbill et al. (2001) and Janson et al. (2006) found that four-premolar extractions require a greater mean treatment duration than two-premolar extraction cases by 2.5, 2.3, and 4.6 months, respectively. Similarly, Cansunar and Uysal (2014a) also reported an increase in treatment duration in their four-premolar extraction group (30.73 months) compared to the two-premolar extraction (27.70 months) and non-extraction groups (22.41 months). This may be due to the time required to correct the molar relationship, agreeing with Fink and Smith (1992) who reported that each extracted premolar adds 0.9 months to the treatment duration. Delayed extraction has also been shown to increase the treatment duration significantly. Skidmore et al. (2006) mentioned that on average an additional 3.3 months will be added to the treatment if extractions are involved (24.6 months) compared to non-extraction cases (21.3 months) and a further 5.9 months will be added

if the extractions were delayed to the middle of treatment (27.2 months). Janson et al. (2007) also reported that cases with delayed extractions had significantly longer mean treatment duration (34.21 months) than immediate extraction cases (23.60 months).

To summarise the influence of extraction on treatment duration from this review; the first group of studies was designed primarily to compare extraction and non-extraction patients retrospectively in order to identify the impact of extractions on treatment outcomes (Vig et al., 1990; Popowich et al., 2005 and 2006; Janson et al., 2007 and 2012). These studies showed no significant impact of extractions on treatment duration, with an exception if the extraction was carried out immediately which was associated with shorter time (Janson et al., 2007). Vig et al. (1990) concluded that extraction could elongate treatment duration, however, this was obscured by confounding variables in their total sample and needed further specific investigation.

The second group of studies was conducted on borderline cases to detect the influence of extraction and non-extraction on treatment outcomes (Lim et al., 2008; Xu et al., 2006; Germeç and Taner, 2008). Among these studies, only the study by Germeç and Taner (2008) was randomised and prospective, while the two others were retrospective. They all found that extractions have increased treatment duration. This finding was similar to that of the third group of retrospective studies which did not primarily compare extraction and non-extraction patients but were designed to explore the contributing factors to treatment duration. An exception of the third group was four studies where no significant relations were found (Taylor et al., 1996; Beckwith et al., 1999; Firestone et al., 1999a; Melo et al., 2013).

The results from the above review are not conclusive. Although the majority of studies have concluded that extractions may increase treatment duration, the treatment mechanics and appliances used for the treatment of Class II non-extraction cases might

also increase treatment duration when compared to extraction cases. As a result, the effect of extractions on treatment duration is still controversial/uncertain.

2.1.1.2.2 Phases of Treatment

Orthodontic treatment sometimes requires two or more phases especially in cases with a skeletal discrepancy where growth modification is required before commencing fixed appliance treatment. Logically, two or more phases will increase treatment duration and several studies have compared single and multiple phases in terms of treatment duration.

Almost all studies that have compared single phase and multiple phases of treatment, whether randomised clinical trials (Tulloch et al., 1998) or retrospective studies (Vig et al., 1990; O'Brien et al., 1995; Beckwith et al., 1999; Turbill et al., 2001; von Bremen and Pabcherz, 2002; Janson et al., 2007; Cançado et al., 2008) have agreed that treatment duration is considerably longer for two or multiple phases of treatment. One study by Janson et al. (2012) found longer treatment duration for two-phase treatment when compared to one-phase treatment but was not statistically significant. This result should be interpreted with caution as it may be due to the relatively small sample size. Therefore, there is sufficient evidence to confirm that two or multiple phases of treatment can result in increased treatment duration.

2.1.1.2.3 Scheduled Appointment Intervals

There are few available studies that have considered the influence of scheduled appointment intervals on treatment duration. Popowich et al. (2005) found that the interval between appointments had a weak but significant positive association with treatment duration. Vu et al. (2008) also reported that increasing the number of active visits per month was significantly associated with reduced treatment duration. Similarly, Ang and Umesan (2011) found that long intervals between appointments resulted in

longer treatment duration. However, Alger (1988) concluded that treatment time might not be affected by increasing the interval between visits from four weeks to six weeks, but he did not have a group with a four-week interval to compare with his six-week interval patients to support this claim.

2.1.1.2.4 Type of Orthodontic Appliance

Two retrospective studies were designed primarily to investigate treatment duration and outcomes between two groups of patients who were treated with 0.018-inch and 0.022-inch slot brackets (Amditis and Smith, 2000; Detterline et al., 2010). The study by Amditis and Smith (2000) included 64 consecutive patients treated by one clinician, while that by Detterline et al. (2010) included 828 consecutively treated patients in a university graduate orthodontic clinic (Table 6). The latter study involved multiple operators.

Neither study provided a clear list of inclusion criteria. Although Amditis and Smith (2000) included different types of extractions (such as incisor extraction) and surgical cases (albeit low percentages) compared to the study by Detterline et al. (2010) who excluded them, Amditis and Smith were more strict in their sample selection. Furthermore, Amditis and Smith (2000) tried to distribute initial variables evenly between the two groups of bracket slots, such as similar treatment technique, gender distribution, number and type of extractions, and mean age. However, other initial variables, such as Wits value were not controlled in a similar way. Interestingly, these two studies (Amditis and Smith, 2000; Detterline et al., 2010) found a statistically significant shorter mean treatment duration with the 0.018-inch slot brackets (20.2, 30.2 months, respectively) when compared to the 0.022-inch slot brackets (21.7, 34.1 months, respectively), but the authors of both studies reported that these differences were not of clinical significance. Additionally, Amditis and Smith (2000) found that

treatment duration for various Angle's malocclusion types were generally shorter with the 0.018-inch slot appliances, although there was a minimal difference in the treatment duration for Class II division 1 cases between the two groups (0.2 months). No statistical test was used to investigate the significance of these findings due to the small numbers in each group of malocclusion.

In their retrospective study, Beckwith et al. (1999) identified that treatment with 0.018-inch brackets was associated with shorter treatment duration, but they reported that this result might be a coincidental finding. Although the study by Vu et al. (2008) was not designed primarily to compare the two bracket slot systems, they also noticed significantly shorter mean treatment duration (9.5 months) for patients treated with 0.018-inch slot appliances than those treated with 0.022-inch slot appliances. However, the authors stated that sample bias was present in this study because of patients who were treated with 0.022-inch slot appliance comprised only 20% of the total sample and they had difficult problems that required adjunctive surgery or treatment with the Tweed technique. Moreover, the study included both optimally finished and prematurely terminated cases. All these factors may together have resulted in a substantial bias.

The available evidence investigating the differences in duration and outcomes of treatment between the 0.018-inch slot and 0.022-inch slot brackets is in favour of the 0.018-inch slot appliances. However, the few studies that are available and their retrospective nature with a high risk of bias necessitate further well-designed prospective randomised clinical trials to be carried out to confirm the exact difference in duration and outcomes of treatment between these two bracket slot systems. The results from such studies will be of use for patients, orthodontists and supply companies throughout the world.

Table 6: Summary of studies that have investigated the influence of bracket slot size on treatment duration

Study	Amditis and Smith	Detterline et al.	Vu et al.
Study design	Retrospective	Retrospective	Retrospective
Year	2000	2010	2008
Sample	64	828	455
Mean age (years)	0.018'' group: 15.6 0.022'' group: 14.9	16.3	16.3
Clinic setting	Private practice	Teaching hospital	Teaching hospital
Operator	Single	Multiple	Multiple
Appliance prescription	Roth	Not mentioned	Not mentioned
Types of Malocclusion	Mixed	Mixed	Mixed
Mean treatment duration (months)	0.018'' group: 20.2 0.022'' group: 21.7	0.018'' group: 30.2 0.022'' group: 34.1	0.018'' group: 27.14 0.022'' group: 36.68
Index for occlusal outcome	PAR (but not presented)	ABO CR-EVAL	ABO CR-EVAL and IUSD (CCA)

Conventional and self-ligating brackets have been compared by several studies. The conclusions of the two systematic reviews by Chen et al. (2010a) and Fleming and Johal (2010) have suggested that the evidence to support one type against the other is lacking.

2.1.1.3 Operator and Health Care Setting Factors

The influence of operator changes on the duration of orthodontic treatment has also been studied retrospectively by McGuinness and McDonald (1998), where two groups of patients were identified who had been treated similarly in terms of the type of pre-adjusted edgewise appliance, interval period between appointments (5-6 weeks), and number of missed appointments. Group 1 consisted of patients who were treated solely by one postgraduate clinician (treatment started and finished by one operator), while group 2 consisted of patients who had their treatment started by another operator and then referred to the same postgraduate clinician as in group 1 to complete their treatment (treatment started by one operator and finished by another one). Thirty patients were randomly selected from each group (however the randomisation method was not mentioned in the study report) and the results showed that there was no significant difference between the two groups in their quality of treatment as reflected

by the PAR scores. However, the mean treatment duration was significantly shorter for group 1 who were treated by one operator (17.67 months) than that of group 2 who were treated by more than one operator (26.1 months).

Qualifications of the operator have also been subject to investigation and it has been found that specialist orthodontists can provide a better quality of treatment outcomes (Abei et al., 2004; Marques et al., 2012) in shorter treatment duration (Marques et al., 2012) than general dentists. Whereas Turbill et al. (2001) mentioned that treatment by a practitioner with an orthodontic qualification required nearly two months more on average than that by other practitioners and this was one of the factors found in the study that was associated with longer treatment duration.

One of the concerns of patients seeking orthodontic care is related to the difference in quality provided by teaching and private practices. This quality of treatment in terms of change in the PAR scores and duration of treatment has been compared between treatment provided by private (specialist orthodontists) and educational (graduate orthodontic residents) clinical settings in Ohio (Mascarenhas and Vig, 2002). The results revealed that post-treatment occlusal outcomes were not significantly different between both clinical settings, while the mean treatment duration was significantly higher for patients treated in private practice (33.0 ± 18.5 months) than those who were treated in a university hospital (27.5 ± 11.8 months). The authors explained this difference in duration due to a greater number of young patients with the mixed dentition in the private practice than in the graduate practice. Moreover, the authors highlighted the presence of investigator and selection bias that might influence the results in spite of all the efforts to control the confounding variables. On the other hand, Cook et al. (2005) found that neither treatment duration, nor, the quality of treatment

(overall ABO CR-EVAL) significantly differed between patients treated in a private practice and those in a university setting.

This review focused on the major factors influencing the duration of orthodontic treatment. Studies that were considered to be out of the scope of the present investigation were not taken into consideration. These include studies comparing different types of appliances (removable, functional, and orthopaedic); different types of brackets (including plastic, ceramic, composite, self-ligating, Begg, and Tip-Edge); and surgical or cleft lip and palate treatment. It can be concluded from this review that:

1. Age (whether chronological or dental) and gender have not been confirmed to play a significant role in predicting the duration of orthodontic treatment and investigations of these are highly affected by confounding factors.
2. Ethnicity and socioeconomic/socio-demographic status do not influence treatment duration according to the available evidence.
3. Pre-treatment Class II malocclusion (dental and skeletal) has a tendency to increase treatment duration, especially when compared to Class I malocclusion.
4. The majority of studies showed that an increase in the pre-treatment severity of malocclusion has been associated with longer treatment duration. Similarly, inferior treatment outcomes have also been correlated with longer treatment duration.
5. Poor patient cooperation elongates treatment duration
6. Although the effect of extractions on treatment duration is uncertain, it may have a tendency to increase treatment duration.
7. Appropriate evidence is available to confirm that two or multiple phases of treatment result in longer treatment duration.
8. Long intervals between appointments result in longer treatment duration
9. Retrospective studies show that 0.018-inch slot bracket systems are associated with shorter treatment duration in comparison to 0.022-inch slot brackets. However, this

is not confirmed yet by a randomised clinical trial (which is the topic of the current thesis).

10. Treatment by an orthodontically qualified practitioner has not been confirmed to influence treatment duration
11. A wide range of variation in treatment duration occurs among patients, even when they have comparable socio-demographic characteristics and are treated using similar techniques. This may be due to the hidden influence of individual variabilities, such as high density of alveolar bone, low bone turnover, thick fibrous gingival tissue and minimal inter-occlusal space.

The current study was designed to be a prospective randomised clinical trial that compares treatment technique (different slot sizes) to avoid the shortcomings of previous heterogenous retrospective studies. Different patient-related and treatment-related factors were recorded which enable the evaluation of their effect on duration of orthodontic treatment.

2.2 QUALITY OF ORTHODONTIC TREATMENT OUTCOMES

2.2.1 Occlusal Indices

Different indices have been developed to measure the severity of malocclusion, treatment need, treatment outcomes and the degree of improvement with orthodontic treatment. For example, the American Board of Orthodontics Discrepancy Index (ABO-DI) is an objective tool that has been accepted as a reliable index for evaluating the complexity of cases based on pre-treatment orthodontic measurements taken from models, cephalometric and panoramic radiographs (Cangialosi et al., 2004). Other indices such as Treatment Complexity index (TCI) and Salzmann Index have also been developed to evaluate the pre-treatment severity of orthodontic cases (Vu et al., 2008; Salzmann, 1967).

The Index of Orthodontic Treatment Need (IOTN) was developed to quantify orthodontic treatment need and it consists of two components; the Aesthetic Component (AC) and the Dental Health Component (DHC). The AC is based on patients perception of their attractiveness by selecting one photograph that resembles their teeth from a series of ten intra-oral colour photographs of teeth in occlusion showing different level of attractiveness from 1 (most attractive) to 10 (least attractive), while the DHC is based on either an intra-oral assessment or a study model assessment, supplemented with information on missing, ectopic, and impacted teeth where relevant (Brook and Shaw, 1989).

One of the most commonly used indices to assess treatment outcome is the Peer Assessment Rating Index (PAR index) which was developed and validated to estimate the degree of deviation of individual cases from normal alignment and occlusion by converting the occlusal anomalies into an overall score. A single summary score

represents the degree of malocclusion, while the difference between pre-treatment and post-treatment scores represents the degree of improvement. It had been weighted originally according to a British standard (Richmond et al., 1992a). However, its flexibility has allowed it to be weighted according to other standards e.g. American weighting (DeGuzman et al., 1995). The PAR index has been used widely in longitudinal orthodontic studies (Bellot-Arcís et al., 2012).

The Index of Complexity, Outcome, and Need (ICON) was developed by Daniels and Richmond in 2000 to evaluate the complexity of a case, as well as treatment need and outcome (Daniels and Richmond, 2000). It is based on the IOTN and PAR indices.

The American Board of Orthodontics Cast-Radiograph Evaluation (ABO CR-EVAL) which was introduced in 1999 to evaluate orthodontic treatment outcomes has been subsequently considered as a stringent and objective index when compared to other indices (Abei et al., 2004; Onyeaso and Begole, 2007; Cansunar and Uysal, 2014b). Hildebrand et al. (2008) considered the ABO CR-EVAL as the current gold standard for assessing study models of orthodontically treated cases. Due to the sensitivity and specificity of the ABO CR-EVAL over other indices, it was selected for use in the current randomised clinical trial to compare treatment outcomes between cases treated with 0.018-inch and those treated with 0.022-inch bracket slot systems.

2.2.2 The American Board of Orthodontics Cast-Radiograph Evaluation (ABO CR-EVAL)

2.2.2.1 Development of the Cast-Radiograph Evaluation

Several indices have been developed to evaluate the quality of treatment (Eismann, 1974; Gottlieb, 1975; Berg, 1979; Eismann, 1980). The majority of the previously developed indices depend principally on the comparison of post-treatment and pre-treatment records. However, they are neither sufficiently accurate nor has their reliability and validity been determined to be adequate. Other indices, such as the Occlusal Index (Summers, 1971) are more suitable for scoring pre-treatment as opposed to post-treatment records. Although the Peer Assessment Rating index (PAR) (Richmond et al., 1992a), has good reliability and validity, it is not sufficiently precise to detect minor discrepancies of tooth position in comparison to the ABO system (Casko et al., 1998). In an attempt to provide a valid and reliable index to objectively assess the outcomes of completed orthodontic cases submitted for the phase III clinical examination of the board-certification process and after a series of four-field tests over a period of five years, the American Board of Orthodontics developed the Cast-Radiograph Evaluation (CR-EVAL) (known previously as the Objective Grading System ABO-OGS) to evaluate post-treatment models and panoramic radiographs. Using this tool, the clinical examination is widely known to be fair, assuming all examination candidates select their cases according to appropriate criteria in order to meet the Board standards.

The ABO CR-EVAL was developed through a series of four comprehensive tests that started in 1995 with 15 measurement criteria for 100 sets of post-treatment models and panoramic radiographs. The subsequent field tests were carried out in 1996, 1997, and 1998 with larger samples used to identify the criteria where inadequacies within the final results frequently occurred. In 1999, based on the results of previous field tests, the

ABO officially produced the OGS (CR-EVAL) as an objective index for grading models and panoramic radiographs and also to create standards for successful completion of orthodontic cases. They also provided a new measurement instrument to assist in the reliability of the measurement process. This system was designed to improve examiner reliability and simultaneously assist the examinee to score their cases during their preparation for the clinical examination, in order to select cases that will successfully pass the ABO CR-EVAL. The final ABO CR-EVAL included eight criteria, namely; alignment/rotation, marginal ridges, buccolingual inclination, overjet, occlusal contacts, occlusal relationship, interproximal contacts, and root angulation (Casko et al., 1998).

Post-treatment study models and panoramic radiographs are measured according to the above eight criteria and scored 0, 1, or 2 depending on the amount of deviation from the standards established by the ABO (Table 7). The sum of points of these criteria for each treated case represents the overall score of the ABO CR-EVAL. Generally, a total ABO CR-EVAL score loss of less than 20 points is considered as satisfactory to meet the ABO standards and can pass the clinical case report portion of the phase III examination. A total score of 20-30 points is subjected to re-evaluation and then will be passed or considered incomplete according to the Board’s decision, while a total score of more than 30 points is regarded unacceptable or incomplete (Casko et al., 1998). Some studies have excluded the root angulation measurement from the total score and have thus adopted a modified cut-off value for a case that would meet the ABO standards to be considered satisfactory (Chaison et al., 2011; Song et al., 2013).

Table 7: The ABO CR-EVAL (Casko et al., 1998; Schabel et al., 2008)

Component	Deduction	Component	Deduction
Alignment/Rotations		**Occlusal relationships**	
< 0.5 mm	0	< 1 mm	0
0.5 to 1 mm	1	1 to 2 mm	1
> 1 mm	2	> 2 mm	2
Marginal ridge height		**Overjet**	
< 0.5 mm	0	0 mm	0
0.5 to 1 mm	1	Less than 1 mm	1
> 1 mm	2	> 1 mm	2
Buccolingual inclination		**Interproximal contacts**	
< 1 mm	0	< 0.5 mm	0
1 to 2 mm	1	0.5 to 1 mm	1
> 2 mm	2	> 1 mm	2
Occlusal contacts		**Root angulation**	
0 mm	0	Root parallelism	0
< 1 mm	1	Roots are not parallel	1
> 1 mm	2	Contacting adjacent tooth	2

2.2.2.2 ABO CR-EVAL and Orthodontic Treatment Outcomes

Successful treatment outcome has differing meaning for different stakeholders. For patients, this is mainly related to the aesthetic improvement with treatment; while according to the ABO success is related to a functional occlusion demonstrated using articulated dental models and parallel roots on panoramic radiographs (Casko et al., 1998; Schabel et al., 2008). Several studies have used the ABO CR-EVAL as an index to assess orthodontic treatment outcomes. Nett and Huang (2005) investigated long-term post-treatment changes using six of the eight ABO CR-EVAL categories (interproximal contacts and root angulations were excluded). The average overall ABO CR-EVAL score showed a significant improvement with time from the post-treatment period (immediately after treatment) to the post-retention period (at least 10 years post-retention), the total CR-EVAL score was 21.46 for post-treatment and 17.58 for post-retention periods. Unlike other categories, only the alignment scores worsened over time. It have also been found that well-finished cases tended to deteriorate with time; whereas, poorly-finished cases tended to improve. However, the study showed some

limitations, for example, those related to generalisability because the sample was limited to a white adolescent population. Moreover, two parameters were not included in the ABO CR-EVAL which might not reflect the actual CR-EVAL score.

Comparison of orthodontic treatment outcomes for early treatment during the mixed dentition with that of later treatment in the early permanent dentition had been investigated retrospectively by Hsieh et al. (2005). Records of 512 orthodontic patients treated in Indiana University were used and the results did not reveal a significant difference in the ABO CR-EVAL scores between early and late treatment.

Schabel et al. (2008) evaluated the correlations between the components of the ABO CR-EVAL and smile aesthetics to identify whether they could be achieved simultaneously or not. It was found that neither the individual components nor the total score of the ABO CR-EVAL could predict attractive or unattractive smiles due to the very weak relationship between them. The study suggested including additional criteria to the ABO CR-EVAL for evaluating overall treatment outcomes including the smile, as it does not currently take into account any soft tissue measurements.

In recent years, an increasing demand for adult orthodontic treatment has increased the percentage of adult cases that are presented to the ABO for certification. Chaison et al. (2011) performed a study to determine if adequately treated adult cases can pass the ABO clinical examination using the CR-EVAL. They used post-treatment study models of 35 adult patients (older than 30 years at the start of treatment) who were treated in a university hospital. Four expert examiners ranked the models into higher-ranked (best-treated) and lower-ranked (worst-treated) groups, then the models were measured using the CR-EVAL without including the root angulation assessment and accordingly a total CR-EVAL score of 27 points or less was considered as a pass. An interesting finding of this study was that having missing teeth could improve the CR-EVAL score as fewer

teeth are scored. Moreover, since the posterior teeth are scored more than the anterior teeth in the ABO CR-EVAL, missing posterior teeth can affect the score more than missing anterior teeth. A similar inequality in the method of scoring teeth with the ABO CR-EVAL was also reported by Lieber et al. (2003). This finding was reflected in the study result when the cases that did not pass in the higher-ranked group were cases that had no missing teeth. Conversely, cases that passed within the lower-ranked group had multiple missing posterior teeth. In spite of the sample bias which resulted from a large number of missing records in that study, it concluded that the ABO CR-EVAL is applicable for adult patients and adequately-treated adult cases can pass the ABO clinical examination using the CR-EVAL (Chaison et al., 2011).

Song et al. (2013) conducted a study to validate the ABO CR-EVAL for assessing treatment outcomes of Chinese patients. It was found, based on the subjective assessment of 69 experienced Chinese orthodontists, that the ABO CR-EVAL is a valid index for evaluating treatment outcomes. Additionally, no statistically significant differences were found between the ABO CR-EVAL scores of patients with different pre-treatment Angle classifications. The authors recommended, for Chinese patients, that a total ABO CR-EVAL score of less than 16 points should be considered as “satisfactory”, 16-21 points as “acceptable”, and scores greater than 21 points as “unacceptable”. They explained the reason for this lower cut-off value compared to that recommended by the ABO was due to the exclusion of the root angulation category from the final measurements in their study in addition to the variation in the gold standards accepted in China and United States. Furthermore, it was mentioned that for treatment outcomes to be comprehensively evaluated, skeletal, dental, and soft-tissue cephalometric measurements, as well as the appropriateness of the treatment plan should also be taken into consideration.

2.2.2.2.1 ABO CR-EVAL and Orthodontic Treatment Outcomes with Different Treatment Techniques and Appliance Types

Attempts have been made to investigate orthodontic treatment outcomes with different appliances using the ABO CR-EVAL. The influence of bracket slot differences on treatment outcomes was investigated retrospectively by Detterline et al. (2010). Records of 613 patients treated with 0.018-inch slot brackets and 215 patients treated with 0.022-inch slot brackets in a university graduate clinic were collected and compared. The results showed that the mean total ABO CR-EVAL score was statistically significantly better for the cases treated with 0.018-inch brackets than those with 0.022-inch brackets (26.3 ± 10.0 and 28.5 ± 11.3, respectively) and this was mainly due to significant differences in the scores of the alignment/rotation category. Since the authors considered a total ABO CR-EVAL score difference of five points to be of clinical importance, the above difference was not regarded to be clinically significant, despite it being statistically significant. This encouraged the authors to support the use of one slot size of brackets instead of multiple appliances as suggested by Rubin (2001), Peck (2001) and Kusy (2002).

The ABO CR-EVAL has also been used to evaluate treatment outcomes for the Roth and MBT bracket prescriptions in a retrospective cross-sectional study by Jain et al. (2013). Records of 20 patients in each group who were treated in a university clinic with 0.022-inch brackets were stratified according to their pre-treatment characteristics and subsequently analysed. The MBT bracket group were found to have statistically significantly better scores than Roth bracket group for buccolingual inclination and occlusal contact categories. The mean difference in total ABO CR-EVAL score was 2.65 points in favour of the MBT group, reflecting that treatment outcomes were better with the MBT prescription brackets than with the Roth prescription. Whilst this difference was statistically significant, it was not clinically significant.

In both the studies by Detterline et al. (2010) and Jain et al. (2013), neither variation in bracket slot nor in bracket prescription were shown to be of clinical significance, but it may be noted that the MBT prescription with a 0.018-inch bracket slot system could result in better treatment outcomes. However, this is required to be confirmed by a prospective clinical trial.

Table 8 shows different studies that used the ABO CR-EVAL to compare orthodontic treatment outcomes with different treatment techniques and appliances. It is worth noting that when comparing different appliances such as Invisalign and fixed appliances or labial and lingual appliances, the level of experience of clinicians for both appliances should be comparable for such a comparison to be scientifically valid. This was not the case for the mentioned studies, therefore these can be a subject of debate due to performance bias resulting from variation in clinical experience.

Table 8: Studies that have used the ABO CR-EVAL to evaluate orthodontic treatment outcomes with different treatment techniques and appliance types

Study	Djeu et al.	Kuncio et al.	Detterline et al.	Jain et al.	Deguchi et al.	Li et al.
Study design	Retrospective	Retrospective	Retrospective	Retrospective	Retrospective	Randomised controlled trial
Year	2005	2007	2010	2013	2015	2015
Sample	96	22	828	40	49	152
Comparison groups	Invisalign system versus the Tip-Edge fixed appliances	Invisalign system versus the Tip-Edge fixed appliances	0.018-inch versus 0.022-inch bracket slot systems	Roth versus MBT bracket systems	Lingual versus labial orthodontic appliances	Invisalign system versus fixed appliances
Total CR-EVAL	Invisalign: 45.35 Tip-Edge: 32.21	Invisalign: T1*: 39.45, T2*: 40.18 Tip-Edge: T1: 43.00, T2: 40.45	0.018'': 26.30 0.022'': 28.50	Roth: 23.85 MBT: 21.20	Labial: 24.50 Lingual: 25.30	Invisalign: 24.49 Fixed: 20.11
Outcome	Treatment with the Tip-Edge fixed appliance is significantly better than that with the Invisalign system	Treatment with the Invisalign showed more relapse than that with the Tip-Edge	Treatment with 0.018-inch brackets is better than that with 0.022-inch (Statistical significant but not clinical)	Treatment with MBT brackets is better than that with Roth (Statistical significant but not clinical)	No significant differences between the lingual and labial appliances but the root angulation was better in labial group	Both Invisalign and fixed appliances could achieve equally successful treatment for Class I adult extraction cases

*T1: post-treatment, T2: three years post-retention

2.2.2.2.2 ABO CR-EVAL and Orthodontic Treatment Outcomes with and without Extractions

Studies that have evaluated orthodontic treatment outcomes with different modalities of extractions are illustrated in Table 9.

Table 9: Studies that have used the ABO CR-EVAL to evaluate orthodontic treatment outcomes with and without extraction

Study	Farhadian et al.	Anthopoulou et al.	Cansunar and Uysal
Study design	Retrospective	Retrospective	Retrospective
Year	2005	2014	2014a
Sample	60	55	1098
Comparison groups	Non-extraction versus four-premolar extraction Cl I malocclusion	Non-extraction versus four-premolar extraction **borderline** Cl I malocclusion	Compare among non-extraction, two maxillary premolar extraction, and four-premolar extraction
Total CR-EVAL	Non-extraction: 36.58 Extraction: 28.65	Non-extraction: 29.07 Extraction: 27.04	Not reported
Outcome	Treatment with extraction is significantly better than that with non-extraction	No significant differences in the treatment outcomes between groups	No significant differences in the treatment outcomes among groups, but the higher percentage of cases with better occlusion was in non-extraction group

When comparing different extraction patterns, a study by Campbell et al. (2007) did not find any significant difference among their ABO CR-EVAL scores, but they noticed a strong tendency of inferior scores for patients with maxillary second premolar and mandibular first premolar extractions.

As a result of these findings, the influence of extraction on orthodontic treatment outcomes when evaluated by the ABO CR-EVAL is still unclear.

2.2.2.2.3 ABO CR-EVAL and Orthodontic Treatment Outcomes in Different Treatment Settings and Variable Clinician Experience

Table 10: Studies that have used the ABO CR-EVAL to evaluate orthodontic treatment outcomes in different treatment settings

Study	Yang-Powers et al.	Abei et al.	Cook et al.	Marques et al.	Mislik et al.
Study design	Retrospective	Retrospective	Retrospective	Retrospective (blind comparative)	Retrospective
Year	2002	2004	2005	2012	2016
Sample	124	196	139	60	66
Comparison groups	University versus private practices (ABO group)	Specialists versus general practitioners	University versus private practices	Specialists versus general practitioners	University versus private practices
Total CR-EVAL	University group: 45.54 ABO group: 33.88	Specialists: 26.00 GDPs: 29.60	University: 25.14 Private: 25.97	Specialists: 10.60 GDPs: 22.90	University: 25.44 Private: 25.94
Outcome	Treatment in private practice (ABO cases) is better than that in university	Treatment by specialists is significantly better that that by general practitioners	No significant differences between the two settings, but the university group has greater variability for the overall score	Treatment by specialists is significantly better that that by general practitioners	No significant differences between the two settings for the overall score

When looking at the study with the ABO group (Yang-Powers et al., 2002), one of the drawbacks that might be expected is sample bias, since the ABO group included cases that passed the ABO assessment and the fact that candidates usually have up to a year to submit their post-treatment models after appliance removal. This allows more improvement of occlusal settling with time, while the post-treatment models of the university group were generally taken on the day of appliance removal, which in turn could result in bias and confounding. Another study has reported that in spite of the comparable means of overall ABO CR-EVAL in university and private practices, the orthodontists in the private practice had fewer cases with very high or very low scores, so they were consistent in their treatment results. On the other hand, the students in the university programme had greater variability in their results, so their final treatment outcomes were less predictable (Cook et al., 2005).

To conclude, uncertainty exists regarding the treatment setting and clinician experience when evaluating treatment outcomes using the ABO CR-EVAL, but the experience is likely to have a consistently positive impact on final treatment outcomes. The retrospective nature of these studies and the probability of selection bias should be taken into consideration when interpreting these results.

2.2.2.2.4 ABO CR-EVAL vs. Other Indices for Evaluating Orthodontic Treatment Outcomes

Deguchi et al. (2005) evaluated treatment outcomes in the postgraduate orthodontic clinics at Okayama University and Indiana University using different indices; the PAR index, the ABO CR-EVAL, and the Comprehensive Clinical Assessment (CCA) in order to determine if there are any correlations between these indices. The CCA was developed by the postgraduate orthodontic programme at the Indiana University as a post-treatment quality evaluation system to complement the ABO CR-EVAL. It assesses various components, such as facial and dental aesthetics, vertical control, arch forms, root resorption, management of the periodontium, and treatment efficiency (Pinskaya et al., 2004). The study found a significant correlation between the ABO CR-EVAL and the CCA, but neither of them were significantly correlated with the PAR index. The explanation of the non-significant correlation between the ABO CR-EVAL and the PAR index was due to the superior ability of the CR-EVAL to evaluate finished cases in all three planes (first, second, and third order) precisely. Therefore, the conclusion was that the combination of the ABO CR-EVAL and the CCA represent the best available method for evaluation of orthodontic treatment outcomes.

The study by Onyeaso and Begole (2007) was primarily designed to determine the relationships among four indices; the Index of Complexity, Outcome, and Need (ICON), the Dental Aesthetic Index (DAI), the PAR index, and the ABO CR-EVAL. A

secondary aim of this study was to assess whether the ICON can substitute other indices to measure orthodontic treatment complexity, outcomes, and need. Both the PAR and ABO CR-EVAL were significantly correlated with each other, unlike the study by Deguchi et al. (2005). Moreover, the PAR and ABO CR-EVAL showed significant correlations with the ICON for treatment outcomes. It was also found that the ABO CR-EVAL had the most robust standards for evaluating treatment outcomes when compared to both the ICON and PAR despite the radiographic measurement was not included in the ABO CR-EVAL assessment.

Campbell et al. (2007) found a significant positive “but weak” correlation between the ABO-DI and the ABO CR-EVAL, where every 1 point increase in the DI resulted in 0.23 ± 0.06 points increase for the CR-EVAL. Therefore, pre-treatment complexity could influence the treatment finishing. However, no significant differences were found for the CR-EVAL among different malocclusion categories. This was in accordance with the study by Pulfer et al. (2009) who also found a weak positive correlation between the DI and CR-EVAL. On the other hand, a study by Cansunar and Uysal (2014b) could not find a significant correlation between the total ABO-DI and total ABO CR-EVAL scores. Although some DI components significantly influenced the total CR-EVAL score, other studies such as Vu et al. (2008) and Cameron (2010) also failed to find a significant correlation between the DI and CR-EVAL scores.

2.2.2.3 Conventional vs. Digital Techniques of ABO CR-EVAL Evaluation

Table 11 presents studies that have compared the digital versus manual measurement of ABO CR-EVAL.

Table 11: Studies that have compared evaluation of orthodontic treatment outcomes using the conventional and digital ABO CR-EVAL

Study	Costalos et al.	Okunami et al.	Hildebrand et al.	El-Engebawy
Study design	Retrospective	Retrospective	Retrospective	Retrospective
Year	2005	2007	2008	2015
Sample	24	30	36	31
Comparison groups	Digital (using OrthoCAD) versus manual scoring of the CR-EVAL	Digital (using OrthoCAD) versus manual scoring of the CR-EVAL	Digital (using OrthoCAD) versus manual scoring of the CR-EVAL	Digital (using new software) versus manual scoring of the CR-EVAL
Total CR-EVAL	OrthoCAD: 29.67 Manual: 31.17	OrthoCAD: 42.93 Manual: 37.93	Scores from digital models were higher by an average of 9.0 points than that from manual scoring	Reported separately for four examiners in each group
Outcome	No significant differences between the two methods	Manual scoring of the CR-EVAL is significantly better than the digital scoring	Manual scoring of the CR-EVAL is significantly better than the digital scoring	Manual scoring of the CR-EVAL is significantly better than the digital scoring

In spite of the advantages of the OrthoCAD software program, such as the ease of saving the measurements electronically, several drawbacks and limitations have been reported with this program regarding scoring buccolingual inclination, occlusal contacts, and the rotation of second molars, in addition to problems in landmarks identification, incorrect articulation of digital models, superimposition of teeth, and grading of extraction cases. Therefore, unless a new improved version of OrthoCAD (or new software) that solves these problems is developed, the conventional/manual method of scoring the ABO CR-EVAL is still the superior method (Okunami et al., 2007; Hildebrand et al., 2008).

Summary: the ABO CR-EVAL was developed to overcome limitations present in other indices in evaluating post-treatment outcomes. It can be concluded from this review that the ABO CR-EVAL is a valid index that can detect poor tooth positioning more precisely than other indices. The literature suggests adequate training and calibration before using the index in order to ensure sufficient reliability.

2.2.3 Incisor Inclination

In orthodontic treatment, appropriate buccolingual inclination of both anterior and posterior teeth is important to achieve stability and proper occlusal relationship. Maxillary incisor inclination is of principal importance in establishing smile aesthetics, proper anterior guidance, and a solid Class I relationship (Papageorgiou et al., 2016).

The interaction between rectangular archwires and bracket slot results in an axial rotation of the wire in the bracket and this creates a force couple (moment) that produces root movement either buccally or lingually relative to the crown of the tooth (Wagner and Nikolai, 1985; Major et al., 2011; Huang et al., 2012). This type of tooth movement is often called “root torque” or third-order movement (Major et al., 2011). Additionally, the term “play” refers to the angle of freedom of the archwire within the bracket slot. This increases with increasing the difference in size between the archwire and the slot (Meling and Ødegaard, 1998; Arreghini et al., 2014) and it inversely relates to the amount of torque. The play between the archwire and bracket slot is of clinical significance in orthodontics because it determines the amount of archwire rotation within the bracket before it engages the slot walls, enabling it thus to transmit third-order forces to the tooth. Therefore, the effective size of the bracket slot is essential in orthodontic biomechanics (Arreghini et al., 2014).

Several factors can influence torque expression, including the dimensions and material properties of archwires and brackets, the geometry of slot and archwires, the play between the archwire and slot, inter-bracket distance, tooth morphology and bracket position, and archwire ligation mode (Sebanc et al., 1984; Germane et al., 1989; Miethke and Melsen, 1999; Morina et al., 2008; Huang et al., 2009; Archambault et al., 2010; Major et al., 2011; Huang et al., 2012; Sifakakis et al., 2013; Arreghini et al.,

2014; Papageorgiou et al., 2016). Huang et al. (2009) concluded that the torque behaviour was determined by the characteristics of the archwire.

Sarver and Ackerman (2003) and Sabri (2005) emphasised the importance and the dramatic effect of incisor inclination as one of the factors that affect the amount of incisor display during smiling, especially as incisor proclination reduces incisor display resulting in a deterioration of smile aesthetics.

Işiksal et al., 2006 indicated the importance of certain sagittal measurements, such as upper incisor inclination in the aesthetic evaluation of the smile when they compared the attractiveness of the smile in orthodontic patients treated with and without extractions and also for untreated participants with ideal occlusion and balanced faces. The study revealed that there was a significant correlation between the inclination of the upper incisors and the aesthetic scores of the smile, with any increase in the upper incisor-SN angle resulted in a decrease in overall smile aesthetics. Contrary to this, Ghaleb et al. (2011) found that when incisor inclination was above the normal reference values, the smile was preferable in terms of optimum aesthetics. Mackley (1993) reported that adequate torque control of the upper incisors was associated with better smile appearance when compared to smiles with less torque control of the upper incisors (lingually inclined incisors).

Cao et al. (2011) found that both incisor inclination and anteroposterior incisor position could influence smile profile aesthetics. The labial inclination of the upper incisors would adversely affect the smile evaluation, whereas maxillary incisor protrusion was more attractive than retruded incisors.

The variation in torque expression using 0.018-inch and 0.022-inch slot brackets has been the subject of experimental investigations. Arreghini et al. (2014) compared the

torque expression capacity of the two bracket slot sizes with different archwire materials and sizes. They concluded that in real life, the play between archwire and bracket slot was greater than the ideal. Consequently, the torque expression with both bracket slots was less than expected due to this dimensional imprecision of brackets and archwires. The variation in torque expression due to imprecision of archwire dimensions was also reported by other investigations (Meling and Ødegaard; 1998; Joch et al., 2010; Lombardo et al., 2015). In a previous study, the brackets and archwires used in the current RCT were validated for their size using scanning electron microscopy (El-Angbawi, 2013). The study was consistent with the above studies and revealed that the dimensions of the 0.018-inch and 0.022-inch 3M Victory Series bracket slots were greater than the manufacturer's dimensions but still within the DIN standards tolerance limit with an exception for the depth of the 0.022-inch slot brackets which was significantly smaller. Regarding the archwire dimensions, the variation was minimal when compared to the manufacturer's published dimensions.

Sifakakis et al. (2013 and 2014) found in their experimental studies that the combination of 0.017 × 0.025-inch stainless steel archwire with the 0.018-inch slot bracket was more effective in delivering torque than that of 0.019 × 0.025-inch stainless steel wires with the 0.022-inch slot brackets. Similarly, Papageorgiou et al. (2016) conducted an in vitro study to compare torque efficiency of square and rectangular archwires with 0.018-inch slot and 0.022-inch slot brackets. They concluded that rectangular wires and 0.018-inch slot bracket were the best combination to produce torque. However, the study used 0.018 × 0.018-inch, 0.018 × 0.022-inch, and 0.018 × 0.025-inch stainless steel wires with the 0.018-inch slot brackets, while with the 0.022-inch slot bracket they used 0.019 × 0.019-inch, 0.019 × 0.025-inch, and 0.019 × 0.026-inch stainless steel wires. These combinations would logically produce higher torque with the 0.018-inch slot brackets as the amount of torsional play could reach 0° with the largest wire, while it was greater in

the combinations with the 0.022-inch slot bracket. The reason for not using the 0.021 × 0.025-inch stainless steel wire was because it could exert high forces. All of these studies considered the lower wire-slot play as the main reason for favouring the 0.018-inch slot bracket as they standardised the type of brackets, archwires, and the ligation method. However, the nature of these experimental studies makes the comparison with clinical studies difficult.

It has been found from clinical trials that both conventional and self-ligating brackets are equally efficient in their torque expression for both the upper and lower incisors (Pandis et al., 2006; Pandis et al., 2010). As regards bracket prescription, it has been found experimentally when using pre-torqued nickel-titanium wires, MBT bracket prescription delivers greater incisor torqueing moments than Roth and edgewise brackets (Mittal et al., 2013). While in another study, when digital models were used for the evaluation, no significant differences were found between Roth and MBT pre-adjusted edgewise bracket prescriptions in their torque expression for the maxillary and mandibular incisors (Mittal et al., 2015). These studies indicate that the type of bracket might have a little effect on the amount of torque expression.

Adequate incisor inclination should be achieved with orthodontic treatment in order to reach the most acceptable incisor appearance. Measurement of incisor torque is usually carried out clinically using cephalometric radiographs or experimentally using digital models or finite element analysis. No clinical study is available to compare the amount of incisor inclination between the 0.018-inch and 0.022-inch bracket slots. In this study, buccolingual inclination of the maxillary and mandibular incisors will be measured using lateral cephalometric radiographs to compare the two bracket slot size systems.

2.2.4 Anchorage Loss

Anchorage is defined as the resistance to unwanted tooth movement (Proffit et al., 2013). It is one of the most important aspects of orthodontic treatment for the production of aesthetic, functional and stable occlusal results. Therefore, anchorage control and the selection of appropriate mechanics should be determined at the treatment planning stage. Several appliances have been designed to enhance anchorage control. These are either intra-oral or extra-oral devices, such as the transpalatal arch, lingual arch, Nance palatal arch, headgear, or temporary anchorage devices (TADs) (Proffit et al., 2013). Anchorage loss is an unfortunate consequence of levelling and aligning, overjet reduction or space closure and usually occurs to a greater extent in the maxillary arch than in the mandibular arch (Su et al., 2014a) and results in suboptimal treatment outcomes. This, in turn, complicates treatment and can elongate treatment duration when anchorage preparation has not been adequately considered at the start of treatment. As a result, complicated procedures, such as molar distalisation may be required during treatment to resolve this problem.

2.2.4.1 Factors Associated with Maxillary Anchorage Loss

It has been shown that mesial tipping of upper molars normally takes place during orthodontic treatment regardless of other factors, however, certain initial patient characteristics are thought to increase this tipping and loss of anchorage (Su et al., 2014a). These factors include:

- *Growth:* downward and forward growth of the upper arch and dentition can continue up to 25 years of age and this leads to forward tipping of the upper molars and subsequent physiological anchorage loss, especially when combined with orthodontic forces (Iseri and Show, 1996; Su et al., 2014a).
- *Age:* mesial tipping of upper first molars and anchorage loss has been determined to be more significant in adolescents when compared to adults

(Harris et al., 1991; McKinney and Harris, 2001; Xu et al., 2010; Su et al., 2014a). Geron et al. (2003) on the other hand found a higher value of anchorage loss in adults when compared to adolescents, although this was not significant.

- *Gender:* boys are subject to significantly greater anchorage loss and mesial tipping of upper first molars than girls (McKinney and Harris, 2001; Xu et al., 2010; Su et al., 2014a).
- *Malocclusion type*: patients with a Class II malocclusion are more likely to lose anchorage than patients with other types of malocclusion (Su et al., 2014a). This can be explained because patients with a Class II malocclusion had been shown to have distally tipped maxillary molars to a greater extent than in other malocclusion types (Martinelli et al., 2010; Su et al., 2014b), which in turn found to have a significant contribution to anchorage loss (Su et al., 2014a).
- *Pre-treatment angulation of upper first molar:* the greater the pre-treatment distal tipping of upper first molars the more mesial tipping and anchorage loss during treatment (Su et al., 2014a).
- *Crowding and overjet*: although it was thought that arch length deficiency is associated with increased anchorage demand and subsequently anchorage loss, Geron et al. (2003) found that the greater the crowding, the lower the anchorage loss. They also noticed a weak correlation between overjet and anchorage loss.

The above are some important patient-related factors that are associated with loss of anchorage. Treatment-related factors, such as extractions, high frictional resistance, type of tooth movement (bodily movement or torque) and the use of heavy and uncontrolled forces can also play a role in increasing anchorage loss.

Anchorage loss has been investigated with different orthodontic appliances. In their retrospective study, Geron et al. (2003) found that anchorage loss was significantly

greater with labial edgewise appliances when compared to lingual edgewise appliances. Conventional and self-ligating brackets have also been investigated for their potential association with anchorage loss through different study designs. These include retrospectives, RCTs, and systematic reviews with meta-analysis. All have concluded that no significant differences exist between bracket systems in terms of the amount of anchorage loss (Mezomo et al., 2011; De Almeida et al., 2013; Machibya et al., 2013; da Costa Monini et al., 2014; Juneja et al., 2015; Zhou et al., 2015). Rajesh et al. (2014) on the other hand conducted a prospective study and found that anchorage loss during the initial stages of treatment was significantly higher in patients treated with Roth prescription appliances when compared to those treated using MBT prescription appliances. No study to date has investigated the difference in anchorage loss between the 0.018-inch and 0.022-inch bracket slot systems.

2.2.4.2 The Palatal Rugae as a Reference Landmark for the Assessment of Tooth Movement

2.2.4.2.1 Morphology of the Palatal Rugae

The palatal rugae are series of irregular and transversely arranged mucosal ridges on either side of the median palatine raphe in the anterior third of the palate behind the incisive papillae (Simmons et al., 1987; Kapali et al., 1997). It was believed that the palatal rugae have unique characteristics for each individual and thus could be used for determining paternity (Lysell, 1955) as well as a method of identification similar to finger printing (Thomas and Van Wyk, 1987; Hemanth et al., 2010; Rajan et al., 2013; Deepak et al., 2014; Adisa et al., 2014). The palatal rugae are protected from physical trauma and damage (due to high temperatures) because of their position, which enables them to play an important role in forensics (Shukla et al., 2011). Three pairs of palatal rugae (right and left) are usually used during investigations, the first, second, and third rugae. Each of them has medial and lateral ends (Figure 1).

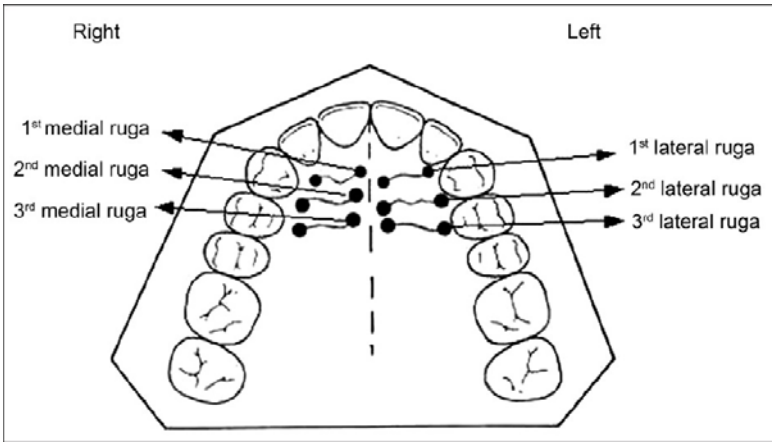

Figure 1: The palatal rugae: The first, second, and third rugae and their medial and lateral points (Abdel-Aziz and Sabet, 2001)

2.2.4.2.2 Stability of the Palatal Rugae

Stability of the palatal rugae has been subject to considerable debate in the literature. Most of these studies have reported a good stability of the whole or certain points of the rugae throughout life or after orthodontic intervention. Carrea (1937) found that the shape of the rugae was not affected after extractions. Lysell (1955), Thomas and Van Wyk (1987) and Hemanth et al. (2010) stated that after reaching their final size, the palatal rugae remain stable throughout life. Additionally, Lebret (1962 and 1964) found that the distances between the rugae points near the median raphe were almost constant and so regarded the palatal rugae as stable reference points that could be used to measure the degree of maxillary tooth migration. Peavy and Kendrick (1967) investigated cases treated with maxillary first premolar extraction and found that the closer the rugae are to the teeth (especially the canines and to a lesser extent the second premolars), the more the tendency to follow tooth movement particularly in the sagittal plane. The study concluded that although alteration of the rugae pattern was minimal, the clinical significance of lateral ends of the rugae as fixed reference landmarks in determining magnitude or direction of tooth movement was limited. Additionally, the study did not evaluate the medial rugae points and molar movement. Van der Linden (1978) assessed the changes in the anteroposterior direction of the rugae and their relationship with the teeth in 65 normally growing children and six orthodontically treated patients. The results of the study revealed significant changes in the rugae and interrugae distances and in the relationship between teeth and rugae in orthodontically treated patients. The authors recommended using the medial rugae points as reference points to evaluate changes in a sagittal positon of posterior teeth due to orthodontic treatment.

Almeida et al. (1995) investigated the stability of the palatal rugae positioning during normal growth and after treatment with headgear and functional appliances for Class II

cases with an early phase of treatment. Dental models of 94 patients were divided into control, headgear, and functional groups and then were evaluated initially and after 15 months. The lateral ruga points showed significant changes in their position in all three groups, but it was the highest in the headgear group; whereas the medial ruga points, particularly the first rugae, did not show any significant positional changes and were therefore considered as good landmarks for the construction of stable reference planes for longitudinal analyses in the anteroposterior and transverse planes. This finding was in agreement with Lebret (1962 and 1964) but was opposite to that by Simmons et al. (1987) who noticed the instability of the medial rugal points.

Bailey et al. (1996) evaluated the influence of orthodontic treatment with and without extraction on the stability of the palatal rugae. Pre- and post-treatment maxillary dental models of 57 adult patients were divided into two groups (extraction of two maxillary premolars and non-extraction treatment). The study revealed that whether patients were treated with or without extractions, the medial and lateral points of the third rugae were stable landmarks for the construction of reference planes for longitudinal assessment of tooth movement in the anteroposterior and transverse directions. This study disagreed with the results of Almeida et al. (1995) regarding the medial points of the first rugae as stable landmarks, but it was almost in agreement with another study by Abdel-Aziz and Sabet (2001) which aimed to assess the stability of the palatal rugae area before and after orthodontic treatment for 50 adult Egyptian patients, who were treated with symmetrical extraction of first premolars. The study concluded that the palatal rugae area was not significantly affected by orthodontic treatment and tooth movement and the lateral third ruga points were the most reliable points that could be used for the superimposition of study models.

In an attempt to determine the relationship of the rugae to the teeth, Hoggan and Sadowsky (2001) designed a study to compare cephalometric superimposition (as an accepted method) and the palatal rugae as reference points for evaluating tooth movement. It was found that study models, especially the medial end of the third palatal ruga, could be regarded as a suitable mean/landmark for assessing anteroposterior incisor and molar movement as with cephalometric superimposition.

Two investigations used a method of superimposition of 3D models on stationary mini-screws as reference points to find out a stable and reliable region on the palate for assessing tooth movement. Jang et al. (2009) concluded that the medial points of the third rugae and the palatal vault are stable landmarks for superimposing 3D maxillary dental model and assessing tooth movement. Chen et al. (2011) also agreed with that finding and considered the medial ⅔ of the third rugae and the regional palatal vault dorsal to it stable and reproducible enough for superimposing 3D models and evaluating orthodontic tooth movement in adult patients.

The medial points of the third ruga have been found to be the most stable in the vertical direction and the least affected by vertical changes over time when compared to the first and second rugae (Christou and Kiliaridis, 2008). Conversely, in the transverse direction, the medial aspect of the third ruga was affected more than that of the first and second rugae following the use of rapid maxillary expansion with fixed orthodontic appliance (Damstra et al., 2009). However, this disagreed with the findings of Bansode and Kulkarni (2009), who stated that the pattern of the rugae morphology was not changed after arch expansion. On the other hand, the impact of orthodontic treatment (with and without extraction and palatal expansion) on the stability of the palatal rugae pattern has been investigated by Deepak et al. (2014). The authors stated that palatal expansion has the highest impact followed by extractions. Therefore, cases requiring

both expansion and extraction showed the greatest changes in the pattern of the rugae. The third rugae were considered fairly stable when compared to the first and second rugae, however, the authors suggested the cautious use of the rugae area after orthodontic treatment.

Bansode and Kulkarni (2009), Shukla et al. (2011) and Stavrianos et al. (2012) conducted comparable studies to evaluate the stability and morphological changes of the palatal rugae following orthodontic treatment. All these studies concluded that in spite of some of the changes that occurred in the rugae due to orthodontic treatment, the morphological pattern of the rugae remained stable and unique for individual patient identification. The study by Shukla et al. (2011) also found that the most stable and reliable points were the medial and lateral third rugae points and they can also be used for the evaluation of tooth movement. The stability of the first and second rugae was influenced significantly by orthodontic tooth treatment. These findings were in line with Mustafa et al. (2015) who stated that the morphological changes in the pattern of the palatal rugae resulting from orthodontic treatment did not seem to influence the uniqueness/individuality of the rugae pattern, but could complicate palatal rugae-based human identification. Therefore, if the palatal rugae are required to be used for human identification, this mandates updating the dental records especially when an orthodontic intervention is undertaken.

It can be concluded from this review of the palatal rugae that the medial points of the third palatal rugae are the most stable reference points and have been successfully used by previous studies for measuring tooth movement and maxillary first molar anchorage loss (Ziegler and Ingervall, 1989; Rajcich and Sadowsky, 1997; Geron et al., 2003; Rajesh et al., 2014).

Table 12: Summary of studies that have evaluated rugae stability

Author	Year	Finding
Carrea	**1937**	The shape of rugae was not affected after extraction
Lysell	**1955**	The palatal rugae remain stable throughout life after reaching their final size
Thomas and Van Wyk	**1987**	
Hemanth et al.	**2010**	The palatal rugae are highly unique and remain stable in shape throughout life
Lebret	**1962** and **1964**	Distances between the rugae points near the median raphe were almost constant. Plaltal rugae could be used as stable reference points to measure maxillary tooth migration
Peavy and Kendrick	**1967**	Rugae closer to teeth have tendency to follow tooth movement especially in sagittal plane and they have limited capability as fixed reference points
Van der Linden	**1978**	There were significant changes in the rugae and interrugae distances and their relationship with teeth due to orthodontic treatment. The medial rugae points preferred as reference points to evaluate sagittal positional change of posterior teeth in such a case
Simmons et al.	**1987**	Medial rugae points was not stable landmarks to measure tooth movement
Almeida et al.	**1995**	The medial rugae points considered as stable landmarks for longitudinal cast analysis, while the lateral rugae points was the opposite
Bailey et al.	**1996**	The medial and lateral points of the third rugae were stable landmarks for patients treated with and without extraction
Abdel-Aziz and Sabet	**2001**	The lateral third ruga points were the most reliable points. The palatal rugae area position was not significantly affected by orthodontic treatment and tooth movement
Hoggan and Sadowsky	**2001**	The palatal rugae especially the medial end of the third rugae could be considered as a stable landmark to assess anteroposterior tooth movement and comparable to cephalometric superimposition
Jang et al.	**2009**	The medial points of the third rugae and the palatal vault are stable landmarks for superimposing 3D maxillary dental model and assessing tooth movement
Chen et al.	**2011**	The medial ⅔ of the third rugae and the regional palatal vault dorsal to it are stable and reproducible enough for superimposing 3D maxillary models and evaluating orthodontic tooth movement in adult patients
Christou and Kiliaridis	**2008**	The medial points of the third rugae can be considered as the most stable and reliable reference points, to identify dental changes, when compared to the first and second rugae (especially for short-term observations)
Damstra et al.	**2009**	The medial aspects of the third ruga were the least stable points in transverse direction after using rapid maxillary expander with fixed appliance when compared to the first and second rugae
Deepak et al.	**2014**	Palatal expansion had the highest impact on the palatal rugae pattern followed by extraction. The third rugae were considered the most stable points when compared to the first and second rugae
Bansode and Kulkarni	**2009**	Some changes occurred in palatal rugae following orthodontic treatment, but the morphological pattern remained stable and unique for individual identification. The pattern of the rugae morphology was not significantly changed after arch expansion, extraction and tooth movement
Shukla et al.	**2011**	Some changes occurred in palatal rugae following orthodontic treatment, but the morphological pattern remained stable and unique for individual identification. The most stable and reliable points were the medial and lateral third rugae points

Author	Year	Finding
Stavrianos et al.	**2012**	Some changes occurred in palatal rugae following orthodontic treatment, but the morphological pattern remained stable and unique for individual identification
Mustafa et al.	**2015**	The morphological changes in the pattern of the palatal rugae resulting from orthodontic treatment did not seem to influence the uniqueness of the rugae pattern but could complicate palatal rugae-based human identification
Ziegler and Ingervall	**1989**	The medial end of the third palatal ruga was used as a stable landmark to assess molar position and canine rotation
Rajcich and Sadowsky	**1997**	The medial end of the third palatal ruga was used as a stable landmark to measure molar and canine movement
Geron et al.	**2003**	The medial end of the third palatal ruga was used as a stable landmark to measure molar anchorage loss
Rajesh et al.	**2014**	

2.2.5 Patient Perception of Orthodontic Treatment

Determining orthodontic treatment outcomes using occlusal indices provides adequate information about the quality of the final occlusion, but fails to evaluate patient experience and satisfaction with treatment. Assessing patient perception can lead to an improvement in the quality of the treatment by determining patient expectations, in particular, identifying unrealistic expectations. Furthermore, this is less expensive and is associated with a higher level of reliability compared to other methods of assessing treatment quality (Rosenthal and Shannon, 1997). Increasing the knowledge base about patient interaction with treatment can increase patient compliance and reduce premature cessation of treatment (Sayers and Newton, 2007). It has also been suggested that the informed consent process should include every aspect of orthodontic treatment including not only the risks and benefits but also information relating to evidence-based patient perception to provide patients with more realistic expectations about the treatment outcome and the possible experiences during the proposed treatment (El-Angbawi, 2013).

Different methods have been used by previous research groups to assess patient perception, such as questionnaires and interviews. As the study reported in this thesis used questionnaires as part of a randomised clinical trial, this review focuses primarily on studies that have employed questionnaires. Some of these questionnaires/scales were restricted to the evaluation of pain and discomfort, using visual analogue scales (VAS), verbal rating scales (VRS), and The McGill Pain Questionnaire. Other studies have however used more comprehensive questionnaires to evaluate the oral health-related quality of life (OHRQoL).

2.2.5.1 Demands and Expectations of Orthodontic Treatment

Several studies have been conducted to identify the reasons why patients seek orthodontic treatment and their expectations before commencing treatment. A list of reviewed studies is available in Table 13.

2.2.5.2 Experience, Impact, and Satisfaction with Orthodontic Treatment

Experience and the impact of orthodontic treatment are usually measured in terms of improvement of the oral health-related quality of life (OHRQoL).

Oral health-related quality of life (OHRQoL) can be defined as "the absence of negative impacts of oral conditions on social life and a positive sense of dentofacial self-confidence" (Inglehart and Bagramian, 2002). It has an essential role in clinical trials to evaluate the consequences of preventive and therapeutic programmes and helping specialists to improve the quality of oral health treatments (Zhou et al., 2014). For these reasons, the World Health Organisation has recommended the importance of including quality of life measures in clinical studies (Cunningham and Hunt 2001; Cunningham and O'Brien, 2007). The quality of life is difficult to assess by a single measure, but some aspects are used to evaluate this such as physical, psychological, social, and functional aspects (Bowling, 2005; Zhang et al., 2006; Zhou et al., 2014). These aspects are directly affected by malocclusion and other dentofacial deformities (Lee et al., 2007; Rusanen et al., 2010).

Examples of the most commonly used disease-specific measures and generic measures to evaluate the OHRQoL with orthodontic treatment include:

- The 14-item Oral Health Impact Profile (OHIP and OHIP-14)
- The Child Perception Questionnaire (CPQ and CPQ_{11-14})
- The United Kingdom Oral Health-Related Quality of Life (OHQoL-UK)

- The Oral Impacts on Daily Performance (OIDP)
- The Short-Form 36-Item Health Survey (SF-36)

Table 13 also presents a list of studies that have reviewed experiences and the impact of orthodontic treatment as well as patient satisfaction. This section is ended with a conclusion of the studies that assessed patient expectations, experiences, and satisfaction with orthodontic treatment, although this was quite difficult due to the heterogeneity of studies.

Table 13: Studies that have reviewed patient perception of orthodontic treatment

Author	Year	Instrument
Observational Studies		
Soltis et al.	1971	Weber ratios to assess force intensity
Klima et al.	1979	Questionnaire
Shaw et al.	1979	Questionnaire
Shaw et al.	1980	Structured interviews and Teacher's Questionnaire
Albino et al.	1981	A series of psychosocial and dental-specific measures
Shaw	1981	Interview and questionnaires (child, parent, teacher)
Tedesco et al.	1983	Dentofacial attractiveness scale
Jones	1984	Discomfort index card
Jones and Richmond	1985	Discomfort index card
Kvam et al.	1989	Questionnaire
Ngan et al.	1989	A series of questionnaires/Visual analogue scale
Wilson et al.	1989	Several visual analogue scales measuring patient perceptions of dental discomfort and psychosocial factors
Brown and Moerenhout	1991	A longitudinal series of four questionnaires
McKiernan et al.	1992	Questionnaires to assess personality traits
Kilpeläinen et al.	1993	Parent-child questionnaire
Dann et al.	1995	Piers-Harris children's self-concept scale
Varela and García-Camba	1995	A series of psychological questionnaires
Scheurer et al.	1996	A series of eight questionnaires including visual analogue scales
Bennett et al.	1997	A developed questionnaire in two forms: Orthodontist Questionnaire and Parent Questionnaire
Sheats et al.	1998	Interview
Tung and Kiyak	1998	Children's and parent's questionnaires
Fernandes et al.	1999	A questionnaire about children's satisfaction and desire for orthodontic treatment: Child's Form and Parent's Form
Firestone et al.	1999b	A pre-treatment questionnaire and then a series of eight questionnaires during treatment. All including visual analogue scales
Khan and Williams	1999	Parents and children were interviewed
Birkeland et al.	2000	A questionnaire about children's satisfaction and desire for orthodontic treatment: Child's Form and Parent's Form; and IOTN (AC and DHC)

Author	Year	Instrument
Shue-Te Yeh et al.	2000	Dental Aesthetic Index (DAI); IOTN (AC and DHC); and Subjective Assessment Questionnaire
Bennett et al.	2001	A developed questionnaire throughout the study (for parents)
Bos et al.	2003	Two questionnaires
De Oliveira and Sheiham	2003	OHIP-14 Questionnaire; Oral Impact on Daily Performance Questionnaire (OIDP); and IOTN (AC and DHC)
De Oliveira and Sheiham	2004	OHIP-14 Questionnaire; Oral Impact on Daily Performance Questionnaire (OIDP); and IOTN-DHC
Erdinç and Dinçer	2004	Questionnaire (including VAS)
Bos et al.	2005	Patient Satisfaction Questionnaire
Larsson and Bergström	2005	Modified version of the Quality from the Patient's Perspective Questionnaire
Reichmuth et al.	2005	Questionnaires completed by children and parents
Al-Omiri and Abu Alhaija	2006	Dental Impact on Daily Living (DIDL) Questionnaire; and NEO Five Factor Inventory (NEO-FFI) Questionnaire
Mandall et al.	2006a	The Impact of Fixed Appliances Questionnaire
Burden	2007	NA
Miller et al.	2007	Daily diary form to measure functional, psychosocial, and pain-related treatment impacts (VAS for pain)
Sayers and Newton	2007	A questionnaire developed for patients' and parents' expectations of orthodontic treatment
Shaw et al.	2007	Set of questionnaires; Interviews; and ICON
Zhang et al.	2007	Child Perception Questionnaire (CPQ)
Bernabé et al.	2008	Oral Impact on Daily Performance Questionnaire (OIDP)
Kiyak	2008	NA
Zhang et al.	2008	Child Perception Questionnaire (CPQ)
Baubiniene and Sidlauskas	2009	Questionnaire about the children's dental appearance and perceived orthodontic treatment need
Hiemstra et al.	2009	A translated version of questionnaire developed by Sayers and Newton (2007)
Krukemeyer et al.	2009	Survey
Taylor et al.	2009	Youth Quality of Life Questionnaire; Children's OHRQoL Questionnaire; Treatment Expectations and Experiences Questionnaire; and Index of Complexity, Outcome, and Need (ICON)
Tecco et al.	2009	The McGill Pain Questionnaire and visual analogue scale
Duggal and Bansal	2010	A translated version of questionnaire developed by Sayers and Newton (2007)
Chen et al.	2010b	OHIP-14 Questionnaire (Chinese version)
Maia et al.	2010	Dental Impact on Daily Living (DIDL) Questionnaire
Wędrychowska-Szulc and Syryńska	2010	Questionnaire
Agou et al.	2011	Child Perception Questionnaire (CPQ_{11-14}); Psychological well-being subscale of the Child Health Questionnaire; and Dental Aesthetic Index (DAI)
Arrow et al.	2011	A questionnaire including: Oral Health Impact Profile Questionnaire (OHIP)-14; Satisfaction with Life Scale (SWLS); and Rosenberg Self Esteem Scale
Costa et al.	2011	Child Perception Questionnaire (CPQ_{11-14}) (Brazilian version); and Dental Aesthetic Index (DAI)

Author	Year	Instrument
Liu et al.	2011a	OHIP-14 Questionnaire; OHQoL-UK Questionnaire;
Seehra et al.	2011	Questionnaires and IOTN (AC and DHC)
Pabari et al.	2011	Valid patient-cantered questionnaire
Wu et al.	2011	VAS to assess oral impacts experienced and treatment satisfaction
Feu et al.	2012	Index of Orthodontic Treatment Need (IOTN-AC and DHC)
Mansor et al.	2012	OHIP-16 Questionnaire (Malaysian version)
Navabi et al.	2012	OHIP-14 Questionnaire (Persian version)
Palomares et al.	2012	Interviews; OHIP-14 Questionnaire (Brazilian version); and IOTN (AC and DHC)
Silvola et al.	2012	OHIP-14 Questionnaire (Finnish version)
Abreu et al.	2013	Child Perception Questionnaire (CPQ_{11-14}) (Brazilian version)
de Souza et al.	2013	Survey
Feu et al.	2013	Interviews; OHIP-14 Questionnaire (Brazilian version); and IOTN (AC and DHC)
Johal et al.	2013	Food Frequency Questionnaire; VAS for pain intensity; and etc.
Keles and Bos	2013	Patient Satisfaction Questionnaire developed by Bos et al. (2005)
Anastasi and Spennato	2014	NA
Baheti et al.	2014	A questionnaire
Brosens et al.	2014	Child Perception Questionnaire (CPQ_{11-14}) (Dutch version); Dutch adaptation of the Harter's Self-Perception Profile for Adolescents (SPPA); and IOTN (AC and DHC)
Feldmann	2014	Questionnaire 1 Concerning Treatment Motivation and Expectations assessed on a VAS; Questionnaire 2 Concerning Satisfaction with Treatment Outcome, Quality of Care and Attention, and Perceived Pain and Discomfort During Treatment assessed on a VAS
Kang and Kang	2014	OHIP-14 Questionnaire (Korean version); and Psychosocial Impact of Dental Aesthetics Questionnaire (PIDAQ)
Magalhães et al.	2014	Evaluation of masticatory and swallowing performances; and VAS used for pain assessment
Marques et al.	2014	Oral Impact on Daily Performance Questionnaire (OIDP); and Global Negative Self-Evaluation Questionnaire
Nagarajappa et al.	2014	The Impact of Fixed Appliances Questionnaire developed by Mandall et al. (2006a)
Silvola et al.	2014	OHIP-14 Questionnaire (Finnish version); VAS to assess aesthetic satisfaction; and IOTN-AC
Abreu et al.	2015	Parental-Caregiver Perceptions Questionnaire (P-CPQ) (Brazilian version)
Abu Alhaija et al.	2015	Dental Impact on Daily Living (DIDL) Questionnaire; and NEO Five Factor Inventory (NEO-FFI) Questionnaire
Azaripour et al.	2015	A specially designed quality-of-life questionnaire
Carter et al.	2015	Interview
Chen et al.	2015a	OHIP-14 Questionnaire (Chinese version); and IOTN-DHC
Farishta	2015	Prepared questionnaire to assess motivating factors and experience with orthodontic treatment
Feldens et al.	2015	Two structured questionnaires, one for adolescents and the second for parents
Johal et al.	2015	Rosenberg Self-esteem Scale; OHIP-14 Questionnaire; and Socioeconomic Status Questionnaire

Author	Year	Instrument
Rakhshan and Rakhshan	2015	Visual analogue scale
Sadek et al.	2015	Validated questionnaire completed by patients and their primary carers
Shahrani et al.	2015	A questionnaire to assess patient satisfaction
Tang et al.	2015	Interview
Tuncer et al.	2015	Questionnaire
van Wezel et al.	2015	Two questionnaires (used by Bos et al., 2003)
Wang et al.	2015	The State-Trait Anxiety Inventory (ST-AI); Visual analogue scale; and The Short-Form 36-Item Health Survey (SF-36) (Chinese versions)
Zheng et al.	2015	OHIP-14 Questionnaire (Chinese version)
de Couto Nascimento et al.	2016	Rosenberg Self-esteem Scale; and a Quality of Life Questionnaire based on the OHIP-14 Questionnaire
Kazancı et al.	2016	Interview
Li et al.	2016	Two questionnaires about expectation, motivation, and satisfaction with orthodontic treatment
Yi et al.	2016	Psychosocial Impact of Dental Aesthetics Questionnaire (PIDAQ); and IOTN-DHC
Prado et al.	2016	Psychosocial Impact of Dental Aesthetics Questionnaire (PIDAQ)
Interventional Studies (Clinical Trials)		
Jones and Chan	1992	Visual analogue scale, questionnaires, and analgesic consumption record
Ngan et al.	1994	Visual analogue scale
Fernandes et al.	1998	Visual analogue scale
Miles et al.	2006	Patient report
Scott et al.	2008a	Visual analogue scale
Fleming et al.	2009b	Questionnaire to assess pain, medication, and anxiety (Anxiety: State-Trait Anxiety Inventory. Pain: visual analogue scale)
Pringle et al.	2009	Pain questionnaire (VAS)
Feldmann et al.	2012	Valid and reliable questionnaire for patient expectations and experiences (developed by Feldmann et al., 2007)
Othman et al.	2014	OHIP-16 Questionnaire (Malaysian version)
Systematic Reviews		
Bondemark et al.	2007	NA
Fleming and Johal	2010	NA
Wang et al.	2010	NA
Jian et al.	2013	NA
Samsonyanová and Broukal	2014	NA
Zhou et al.	2014	NA
Andiappan et al.	2015	Studies used OHIP-14 Questionnaire
Pachêco-Pereira et al.	2015	NA
Yao et al.	2016	NA
Javidi et al.	2017	NA

2.2.5.3 Limitations of Previous Studies Assessing Patient Perception

1. Most studies were observational particularity of cross-sectional design. Moreover, most of the published longitudinal studies have a short follow up period. On the other hand, only a limited number of randomised controlled trials and systematic reviews with meta-analysis have been undertaken.
2. Limitations in sample size and statistical power calculations were noted in some studies (Palomares et al., 2012; Othman et al., 2014; and Wang et al., 2015).
3. The differences or variations in the measures used to evaluate OHRQoL prevented standardisation of the assessment method (Zhou et al., 2014). Moreover, most of the studies were observational and consequently were subject to bias and confounding that adversely affected their validity (Grimes and Schulz, 2002; Zhou et al., 2014). As in any questionnaire study, data could be subject to different sources of bias and errors (Bowling, 2009) resulting from several factors including age, gender, ethnicity, psychological status, and socio-economic status. As a result, confounding is likely to be present in studies of patient perception (Zhou et al., 2014). To further complicate the situation, the meta-analysis by Andiappan et al. (2015) identified publication bias.
4. Most of the measures used in dentistry are not necessarily directly applicable to orthodontics because orthodontics deals primarily with aesthetics, function, and psychosocial concerns instead of pain and discomfort. It is also debatable whether malocclusion and orthodontic care can be considered as a disease/treatment and health-related factor or as a lifestyle choice. This is because orthodontic treatment differs from other medical interventions in that it does not treat a disease process but corrects an abnormality within the face (O'Brien et al., 1998; Kok et al., 2004; Cunningham and O'Brien, 2007).

5. The majority of studies that measure the effect of orthodontic treatment on quality of life had been administered to children and adolescents rather than adults (Zhou et al., 2014). It should be noted there are some difficulties that might be encountered when studying OHRQoL with orthodontic treatments in adolescents and children, due to the fact that the quality of life views of children and adolescents differ to those of adults (Pal, 1996). Furthermore, adults and children have different cognitive capabilities, therefore, an age-specific questionnaire should be designed to solve this problem and to follow the changes in behaviour with age (Jokovic et al., 2002; Cunningham and O'Brien, 2007).

It has been shown that self-perception of minor changes in dental aesthetics (Klages et al., 2004), orthodontic treatment need and malocclusion are significantly associated with a negative impact on OHRQoL (Helm et al., 1985; Mandall et al., 1999; De Oliveira and Sheiham, 2003; Kok et al., 2004; Brown and Al-Khayal, 2006; O'Brien et al., 2006; Wong et al. (2006); Johal et al., 2007; O'Brien et al., 2007; Kiyak, 2008; Liu et al. 2009; Feu et al., 2010; Hassan and Amin, 2010; Rusanen et al., 2010; Agou et al., 2011; Liu et al., 2011b; De Baets et al., 2012; Masood et al., 2013; Dawoodbhoy et al., 2013; Kang and Kang, 2014; Andiappan et al., 2015; Benson et al., 2015; Chen et al., 2015a; Clijmans et al., 2015; Dimberg et al., 2015; Farishta, 2015; Thiruvenkadam et al., 2015; Choi et al., 2016; Kragt et al., 2016). This could primarily be due to the effect of teasing and bullying (among children) and the associated poor self-esteem, social, emotional and psychological well-being.

2.2.5.4 General Conclusion of This Review

1. The aesthetic impact of malocclusion was the highest motive for seeking orthodontic treatment when compared to other motives such as the correction of occlusal abnormalities and an overall functional improvement. This is because patients usually expect an improvement in dentofacial aesthetics from treatment.
2. Orthodontic treatment could result in a deterioration of the quality of life in terms of increasing in pain and discomfort, functional limitation, and deterioration in psychosocial and emotional well-being. This principally occurs during the initial stages of treatment but could be reduced as treatment progresses. Therefore, both a short term and long term evaluation of patient perception is important for successful treatment. O'Brien et al. (1998) and Bennett and Phillips (1999) emphasised that an objective treatment assessment should be supplemented with measures to assess health-related quality of life as determined by patients, where patient satisfaction with treatment and treatment outcomes are not related to clinician opinion or the objectivity of the findings.
3. Adults and females are noted to be more dissatisfied with appearance and were, therefore, more motivated to undergo orthodontic treatment than males and younger patients. Similarly, adults and females may be more sensitive both during treatment and with the final treatment outcome (younger patients particularly are more probably adaptable to treatment), although this is a controversial issue. An increasing expectation of orthodontic treatment was found with age, whilst, gender has not been confirmed to influence expectations of treatment.
4. Ethnicity could influence patient expectation, although this is as yet to be confirmed.
5. Due to the possibility of differences in patient and parent expectations, effective communication between the orthodontist-patient-parent(s) is important. A good orthodontist-patient relationship and meeting the patient's expectations is necessary

in order to achieve good patient compliance during treatment as well as provide satisfaction with the final treatment outcome. However, these expectations should be realistic and sufficient information about all aspects of treatment should be provided before starting treatment.

6. There is still a deficiency in the information and tools that can comprehensively evaluate the impact of fixed appliance orthodontic treatment on the quality of life especially as part of a randomised controlled trial.
7. Further revisions and refinements are required for OHRQoL measures to be more specific for orthodontics. Cunningham and O'Brien (2007) stated: "It also seems sensible that future research work in orthodontics should focus on developing one valid and reliable OHRQoL instrument for use both clinically and in research studies (perhaps with an adolescent and adult version) rather than undertaking studies to develop several new measures." (Cunningham and O'Brien, 2007: 101).

2.3 ORTHODONTICALLY-INDUCED INFLAMMATORY ROOT RESORPTION (OIIRR)

Orthodontic treatment can result in biological adverse effects, including orthodontically-induced inflammatory root resorption (OIIRR), loss of crestal alveolar bone height, TMJ dysfunction, tooth wear/enamel damage on debonding, and demineralisation of tooth enamel. This domain of the study was concerned with OIIRR during the levelling and alignment stage of treatment and has been reviewed comprehensively in the first part of the current randomised clinical trial by El-Angbawi (2013). In this thesis, a short summary will be presented.

Root resorption is a reduction in root structure (Sharab et al., 2015). It can happen due to trauma or orthodontic treatment. However, it can also happen without an obvious cause (idiopathic root resorption) (Lopatiene and Dumbravaite, 2008). Root resorption can be classified into inflammatory resorption (internal/external or progressive/transient) and replacement resorption. Generally, root resorption associated with orthodontic treatment is transient or progressive external inflammatory resorption (Tronstad, 1988).

The rate of incidence of OIIRR as an iatrogenic result of orthodontic treatment varies with different detection methods and may reach rates up to 94% when using cone beam computed tomography (CBCT) (Lund et al., 2012).

Maxillary anterior teeth have been reported to have the highest tendency for root resorption in the dentition (Sameshima and Sinclair, 2001a; Apajalahti and Peltola, 2007). Furthermore, it has been found that maxillary central incisors had the highest percentage of OIIRR followed by maxillary lateral incisors and then mandibular incisors (Beck and Harris, 1994; Janson et al., 2000; Jung and Cho, 2011; Maués et al., 2015).

2.3.1 Factors That May Influence OIIRR

2.3.1.1 Patient-Related Factors

2.3.1.1.1 Age

The evidence available from the few studies that have primarily investigated the effect of chronological age on OIIRR have not revealed age as a significant factor influencing OIIRR. On the other hand, teeth with incomplete root formation before treatment have been found to be less sensitive to OIIRR (Mavragani et al., 2002).

2.3.1.1.2 Gender

Gender has not been confirmed to have a clear and significant influence on the occurrence of OIIRR (refer to the thesis by El-Angbawi, 2013).

2.3.1.1.3 Ethnicity

Although Asians have been found to have a lower susceptibility to OIIRR than Hispanic and white ethnic groups (Sameshima and Sinclair, 2001a and 2001b), further studies are required to confirm the influence of ethnicity on OIIRR.

2.3.1.1.4 Genetics and Individual Susceptibility

The IL-1B polymorphism was found to significantly increase the risk of OIIRR (Al-Qawasmi et al., 2003), but did not account for all of the variances among patients with a high risk of OIIRR. Recently, variations in the osteopontin gene (Iglesias-Linares et al., 2014), polymorphism of the P2RX7 gene (Pereira et al., 2014; Sharab et al., 2015), interleukin IL-6 and IL-6 SNP (Kunii et al., 2013; Guo et al., 2016) were also determined to be risk factors for external apical root resorption. Further studies are required to isolate the suspected genes that responsible for OIIRR and clarify individual variation. Individual variations and susceptibility for root resorption were also reported by different investigations (Owman-Moll et al., 1996a; Owman-Moll et al., 1996b; Han et al., 2005; Lopatiene and Dumbravaite, 2008).

2.3.1.1.5 Systemic Conditions

Some systematic conditions may increase the tendency to OIIRR, such as asthma (McNab et al., 1999) and low thyroid function (deficiency of thyroxine) (Poumpros et al., 1994). On the other hand, there is a contradiction about the capability of bisphosphonate administration to reduce the tendency to OIIRR (Iglesias-Linares et al., 2010).

2.3.1.1.6 Dental Anomalies

There is weak available evidence to support that dental anomalies can increase the possibility of OIIRR (see El-Angbawi, 2013).

2.3.1.1.7 Root Morphology

Some studies have found an association between abnormal root morphology, such as apical pipette shape and a high risk of OIIRR (Levander and Malmgren, 1988; Sameshima and Sinclair, 2001a), however, this finding is not yet supported by strong evidence (see El-Angbawi, 2013).

2.3.1.1.8 Trauma

Traumatised teeth with no signs of root resorption have not been found to have a high risk of OIIRR (Weltman et al., 2010). On the other hand, traumatised teeth with root resorption before orthodontic treatment may have a higher tendency to OIIRR during orthodontic treatment (Malmgren et al., 1982; Levander et al., 1994).

2.3.1.1.9 Type and Severity of Malocclusion

It is difficult to determine if the type of malocclusion can have an influence on OIIRR, but some features of malocclusion such as an increased overjet in Class II division 1 malocclusion may be associated with a high risk of OIIRR (see El-Angbawi, 2013).

2.3.1.2 Treatment-Related Factors

2.3.1.2.1 Treatment Duration

There is a debate about the influence of treatment duration on OIIRR with no clear conclusions. However, it seems that increased treatment duration can increase the risk of OIIRR (Segal et al., 2004; Roscoe et al., 2015).

2.3.1.2.2 Force Magnitude

It has been found that a higher force magnitude can increase the risk of OIIRR. This was confirmed by two systematic reviews (Weltman et al., 2010; Roscoe et al., 2015).

2.3.1.2.3 Type and Amount of Tooth Movement

A higher magnitude of applied moment (torque movement) for a long time period was found to be associated with root resorption (Casa et al., 2001). A systematic review revealed that intrusive and lingual root torque movements were strongly associated with OIIRR (Weltman et al., 2010). Similarly, a meta-analysis revealed that the amount of apical displacement was highly correlated with apical root resorption (Segal et al., 2004).

2.3.1.2.4 Bracket Design

Neither self-ligating versus conventional brackets, nor standard versus pre-adjusted edgewise brackets were found to significantly differ in their influence on the amount of OIIRR during treatment (see El-Angbawi, 2013).

2.3.1.2.5 Bracket Slot Size

No evidence is available to indicate one bracket slot size against the other in terms of OIIRR. However, most of the available studies are either retrospective or confounding with other variables (see El-Angbawi, 2013).

2.3.1.2.6 Archwire Sequence

The few available studies do not reveal a significant correlation between archwire type, size, or sequence and the degree of OIIRR (see El-Angbawi, 2013).

2.3.1.2.7 Extraction vs. Non-Extraction Treatment

There are conflicting results regarding the effect of extractions on OIIRR. Some studies have found that extraction cases are more prone to OIIRR during treatment and this could be due to the higher range of root movement when there is an extraction, whereas others have not found such a correlation (see El-Angbawi, 2013).

In conclusion, for patient related factors, individual susceptibility and the genetic background may have a greater influence than patient demographics, type of malocclusion, and root shape. Regarding treatment-related factors, the magnitude of the force and intrusive tooth movement could have a much higher influence on developing OIIRR. High quality studies are required to investigate the exact influence of different factors on OIIRR.

2.3.2 Detection and Measurement of OIIRR

Different methods have been used to detect OIIRR, these include:

2.3.2.1 Microscopic Investigations

Histological and ultrastructural microscopic techniques, especially scanning electron microscopes, have higher accuracy for detecting OIIRR than radiographic techniques. However, these laboratory techniques cannot be used in clinical research as a clinical diagnostic aid.

2.3.2.2 Radiographic Investigation

These can be easily used in clinical researches, but have limited accuracy for detecting OIIRR because of the two-dimensional nature of the images. Panoramic radiography,

lateral cephalometry, and periapical radiographs are the most commonly used techniques to detect OIIRR. Periapical radiographs can provide a fine detail view of the root and alveolar bone for a limited area. Standardisation of the radiographic technique is necessary before assessing OIIRR in order to reduce orientation, magnification, and procedural errors.

2.3.2.3 Three Dimensional Imaging

This includes CBCT which can detect root resorption with higher accuracy than radiographs but exposes the patient to a higher dose of radiation and this, in turn, might limit its routine use for detecting OIIRR in clinical researches.

2.3.3 Methods of Measuring OIIRR

2.3.3.1 Scoring System

This includes a method developed by Malmgren et al. (1982) to subjectively assess the degree of apical OIIRR using an ordinal scoring system.

2.3.3.2 Linear Measurements

This method is based on linear measurement of the root length from radiographs, after correcting the radiographic magnification (Linge and Linge, 1983; Linge and Linge, 1991).

2.3.3.3 Digital Reconstruction/Subtraction

This method is undertaken by using computer software to calculate root length by measuring the pixels on digital radiographs (Reukers et al., 1998a; Eraso et al., 2007).

2.3.4 Early Detection of OIIRR

It has been suggested that a radiograph is taken at 6-12 months from the start of treatment in order to predict the potential risk of severe OIIRR at the end of treatment. Levander and Malmgren (1988) reported in their retrospective study that all the teeth that had suffered from severe OIIRR at the end of treatment were diagnosed with OIIRR 6-9 months from the start of treatment. Similarly, Ono et al. (2016) stated that the greatest amount of external apical root resorption occurred during the first 6-7 months of orthodontic treatment. Picanço et al. (2013) also found that teeth with initial root resorption at the beginning of treatment have a higher susceptibility to OIIRR during treatment. On the other hand, Makedonas et al. (2013) reported that radiographic examination 3-6 months from the start of treatment might be too early to detect patients that would suffer from severe OIIRR at the end of treatment.

2.3.5 Management of OIIRR

OIIRR can be managed by pausing or terminating the active treatment (Weltman et al., 2010; Roscoe et al., 2015). Schwarz (1932) stated that root resorption can cease and new layers of cellular cementum would be deposited on the resorption crater when the orthodontic force is reduced to below the optimal level (20 to 26 gm/cm^2). Levander et al. (1994) found that changing the orthodontic appliance from active to passive for 2-3 months could reduce the severity of OIIRR in patients with evidence of OIIRR at six months from the start of treatment and this was supported by recent systematic reviews (Weltman et al., 2010; Roscoe et al., 2015).

2.4 RANDOMISED CLINICAL TRIALS (RCTS)

2.4.1 Definition of Clinical Trials

Different definitions have been produced for clinical trials over time. Meinert (1986: 3) defined a clinical trial as “a planned experiment designed to assess the efficacy of a treatment in man by comparing the outcomes in a group of patients treated with the test treatment with those observed in a comparable group of patients receiving a control treatment, where patients in both groups are enrolled, treated, and followed over the same time period”. Piantadosi (1997: 10) defined a clinical trial as “an experiment testing medical treatments on human subjects.” Friedman et al. (2010: 2) defined a clinical trial as “a prospective study comparing the effect and value of intervention(s) against a control in human beings”. Chow and Liu (2014: 4) defined a clinical trial as “a clinical investigation in which treatments are administered, dispersed, or used involving one or more human subjects for evaluation of the treatment.” Clinical trials are usually conducted by pharmaceutical companies and other clinical research centres.

From the above definitions it can be inferred that there are three important component elements in clinical trials (Chow and Liu, 2014):

1. ***Experimental unit:*** this represents a subject from a targeted population under investigation.
2. ***Treatment:*** this can be a placebo or any combination of interventions, such as medical, dental, pharmaceutical, diet, treatment techniques, etc. For example, the assessment of the effectiveness of the treatment of breast cancer by lumpectomy surgery or chemotherapy. Another example is the current study, which investigates the effectiveness of orthodontic treatment delivered by 0.018-inch and 0.022-inch slot bracket systems.

3. ***Evaluation:*** this involves the assessment of the effectiveness and safety of a test treatment. Recently, the assessment of the quality of life in clinical trials has also been introduced as an important aspect to be added to the evaluation of efficacy and safety of the treatment.

2.4.2 Hierarchy of Clinical-Evidence Studies

A properly designed randomised clinical trial provides important scientific evidence for the evaluation of different therapeutic interventions. On the basis of research design, systematic reviews that collect and analyse the best available evidence (especially if the data is derived from multiple RCTs with meta-analyses) are considered as the highest level of evidence in the hierarchy of studies and RCTs are placed as the second highest level of evidence in terms of evaluating the effectiveness of healthcare interventions (Pandis, 2011; Jacobs et al., 2013). Figure 2 illustrates the pyramid of evidence or hierarchy of strength of studies.

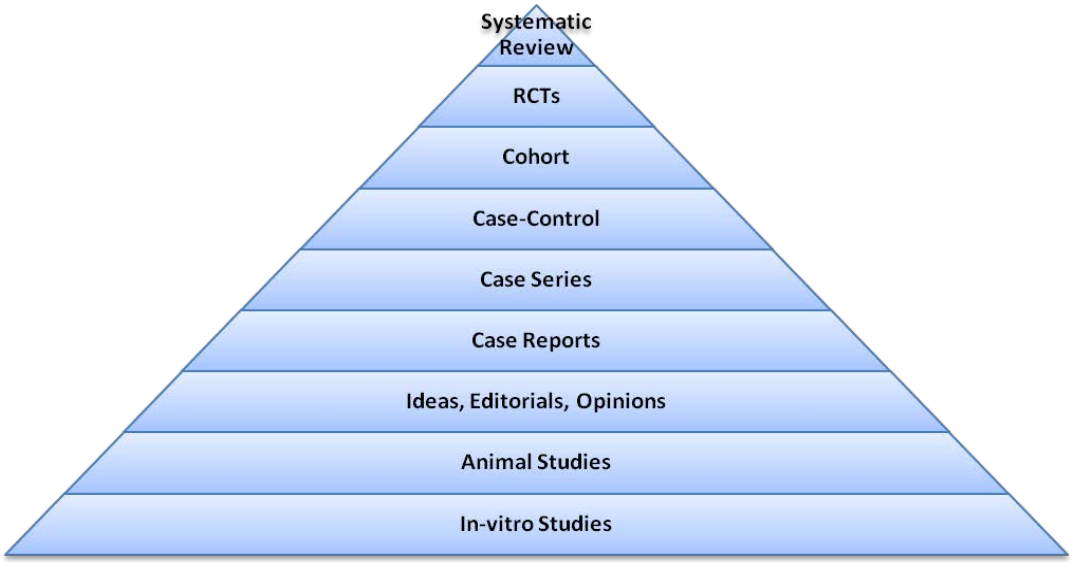

Figure 2: The pyramid of evidence. Hierarchy of strength of studies (Pandis, 2011)

2.4.3 History of Randomised Clinical Trials

The concept of randomisation in clinical trials was not adopted until the early 1920s (Fisher and Mackenzie, 1923). However, randomisation of patients to treatments in clinical trials was first introduced by Amberson et al. (1931) in order to decrease the possibility of bias and increase the statistical power for detecting clinical differences, where the flip of a coin was used to determine which group received the treatment. In the same year (1931), a Therapeutic Trial Committee was appointed by the Medical Research Council of Great Britain (Medical Research Council, 1931). The duty of this committee was to ensure high quality clinical practice by regulating and publishing reports for conducting clinical studies accepted for trials. In 1937, the first research grant in a clinical trial was awarded to the US National Institutes of Health, and in 1944 the Lancet presented the first publication from a multicentre trial "The Patulin Clinical Trials Committee, 1944" (Friedman et al., 2010; Chow and Liu, 2014).

2.4.4 Rationale for Randomised Clinical Trials

The essential goal of RCTs is to minimise bias and maximise the accuracy of the results so that the clinical question under investigation is addressed scientifically. Two types of unbiased trial results were described by Lachin (2000). First, when a comparison between the treatments under investigation is unbiased. Second, where the statistical analysis and outcome assessment of the treatment effect are obtained in an unbiased manner. The accuracy of the results allows the estimated treatment effect based on the data from a clinical trial to be reproduced in the same target patient population and also to be generalised to a different patient population (Chow and Liu, 2014).

The size of the trial should be considered when designing a clinical trial. Accordingly, the clinical question should be specific for a single trial; otherwise, it would be difficult to answer a number of possible study questions relating to a particular therapeutic area

with limited clinical data. Furthermore, this might even jeopardise the project time frame and funding. Therefore, it is preferable for the objective of the clinical trial to be provided as a statement related to the clinical question, which is clear, precise, concise, scientifically valid, and can be easily transformed into hypothesis. In the case of multiple objectives, the investigator should prioritise them into primary and secondary objectives (Chow and Liu, 2014).

2.4.5 Randomisation

In order to ensure the integrity of a clinical trial, randomisation is usually used to control any intentional or accidental bias in the allocation of patients to treatment groups avoiding subjectivity in the assignment of treatments to participants. Consequently, this produces comparable groups with similar characteristics, enhances the validity of the statistical tests for the clinical evaluation as well as enabling the generalisation of the results. Conversely, a non-randomised trial might violate the distribution of the targeted population (patients) and therefore neither accurate nor reliable statistical inferences from the study can be drawn. Randomisation in clinical trials usually consists of both:

1. Random selection of the representative sample from a target patient population.
2. Random assignment of treatments to participants, so each one has an equal chance to receive the treatment/placebo or types of treatment under investigation.

Sometimes, when there is individual variation between groups that will be allocated to different treatment modalities (e.g. different demographic details) it is preferable to use randomisation with stratification to eliminate any possible bias due to such differences. The logic underpinning stratification is to identify the variability between participants and then to arrange them according to these covariates in order to prevent an imbalance between groups with regard to important covariates. For example, if a clinical trial is

conducted to compare a test drug with a placebo, participants should be matched in pairs according to predetermined covariates, such as demographic factors or the severity of the disease. Then within each pair, one subject is assigned to receive the test treatment and the other receives the placebo. By this process, treatment effect inferences can be obtained more precisely and there is a guarantee that no imbalance between groups will be present, such as when one group involves only males while the other recruited females. However, stratification can be complicated and difficult to implement especially as it is impossible to determine all possible covariates. Therefore, failure to include any important covariate could cause unidentified bias. Moreover, if the number of covariates is high, this will necessitate an increase in the sample size, which might jeopardise the study feasibility. Therefore, if stratified randomisation is required in a clinical trial, this should be implemented for the covariates that are vitally important to ensure the integrity of the investigation (Blackwell and Hodges, 1957; Lachin, 1988; Friedman et al., 2010; Chow and Liu, 2014).

2.4.6 Blinding/Masking

Although randomisation can minimise the majority of recruitment, allocation, and observer bias in clinical trials, it cannot avoid bias caused by subjective reporting and data management resulting from the knowledge of treatment allocation during the analysis phase. Therefore, it is mandatory in clinical trials to ensure allocation concealment both during the treatment phase and during the data analysis phase to avoid bias arising from this source. This process is called blinding, sometimes also termed masking. There are four types of blinding/masking (Friedman et al., 2010; Chow and Liu, 2014):

2.4.6.1 Open-Label Trial (Unblinded)

In this type of study, no blinding is applied and both the participant and investigator know which treatment group the participant has been assigned to. It is the weakest form of blinding and bias can occur easily in this type of study. This is why open-label blinding is not recommended for high quality clinical trials. However, it might be the only option due to ethical considerations, such as when the clinical trial is conducted to evaluate the effectiveness and safety of a new surgical procedure.

2.4.6.2 Single-Blind Trial

In this type, either the participant or the investigator is blinded to the allocation of treatment. Usually, a single-blind clinical trial means that the participant has no knowledge of the type of treatment. It is on a higher level than open-label trial, but the investigator is aware of treatment allocation and this may introduce bias to the results.

2.4.6.3 Double-Blind Trial

In this type neither the participant nor the investigator who is responsible for following the participants, data collection, and data analysis should know the type of treatment that is being delivered and as a result, bias is reduced. Any procedure that might unmask the group to the investigator should be undertaken by an outside body who could monitor the trial to ensure participant safety.

2.4.6.4 Triple-Blind Trial

When all the parties of clinical trial (participant, investigator, and the monitoring committee) are blinded then this is known as a triple-blinded trial. This type has the highest level of validity for a clinical trial with the least degree of bias.

It is important to note that there are situations in which it is necessary to reveal treatment allocation during a study. For instance, when there are serious side effects

during treatment or unexpected events; these mandate the clinician and monitoring committee to “unblind” the treatment group (Friedman et al., 2010; Chow and Liu, 2014).

2.4.7 Reporting of Randomised Clinical Trials

2.4.7.1 CONSORT

CONSORT is an acronym for Consolidated Standard of Reporting Trials. It was developed in 1996 by a group of international experts including clinical trialists, methodologists, statisticians, epidemiologists, and journal editors in order to improve the quality of reporting of RCTs (mainly simple two-group parallel RCTs). The CONSORT statement is composed of a checklist and a flow diagram, with both being used for writing, reviewing, and assessing the reports of RCTs. The CONSORT system is flexible in terms of revision, modification, and including new items to accommodate any future requirements. It was first published in 1996 and then revised and updated in 2001 and 2007 (CONSORT 2010). The last version of the CONSORT checklist (CONSORT 2010) consists of 25 key items that should be included when reporting a randomised trial. The accompanying CONSORT flow diagram describes the flow and progress of participants throughout the trial. For example, the number of people assessed for eligibility, the number of subjects excluded (with reasons), the number of subjects allocated to each treatment group in the trial, the number of missing records and reasons for this (dropouts), and the number of patients who were or were not analysed. In addition to providing standards for the design and reporting of a clinical trial, CONSORT can also offer a standard against which different trials can be compared (Begg et al., 1996; Moher et al., 2001; Earl-Slater, 2002; Moher et al., 2010).

2.4.8 Designs of Clinical Trials

Once the study objectives have been determined to answer one or more of the study questions related to the therapeutic intervention(s) under investigation, a suitable design for the clinical trial can be determined to optimise the value of the study. There are different types of clinical trial designs, such as parallel, crossover, cluster randomised, titration, enrichment, sequential, placebo-challenging, and blinder reader designs. The parallel design is the most commonly used type of clinical trial to identify the effectiveness and safety of treatment, in which each patient is randomly assigned to only one treatment. For example, a two-group parallel design (which is the simplest form) is undertaken when one group receives the treatment and the other receives the control. The crossover design is a modified randomised block design, in which each patient receives more than one treatment at different periods. Titration and enrichment designs are also widely used in pharmaceutical clinical trials. Each design has its advantages and drawbacks in specific circumstances. Selection of an appropriate design is an important aspect of the success of a clinical trial and this depends on several factors, such as the study objective, number and characteristics of treatments to be tested, availability of patients and their variability, duration of study, and predicted dropout rates (Chow and Liu, 2014). In the current study, a parallel group design has been employed to compare the treatment effectiveness between the two orthodontic bracket slot systems (0.018-inch and 0.022-inch).

2.4.9 RCTs and Orthodontics

Two retrospective observational studies aimed to identify different types of orthodontic papers published in orthodontic journals (Harrison et al., 1996; Gibson and Harrison, 2011). Harrison et al. (1996) searched for papers published in the *British Journal of Orthodontics* and *European Journal of Orthodontics* from 1989 to 1993. They found that 59.3% of the studies were related to clinical orthodontics and only 2.8% of these were RCTs while the other studies used non-randomised controls or were uncontrolled. Gibson and Harrison (2011) carried out their investigation using the four main orthodontic journals (the *American Journal of Orthodontics and Dentofacial Orthopedics*, the *Angle Orthodontist*, the *European Journal of Orthodontics*, and the *Journal of Orthodontics*) for a period from 1999 to 2008. Only 10.8% of the clinical-based studies were RCTs while other designs, such as case report and case series (which have lower ranks in the hierarchy of evidence concerning the efficacy of treatment) comprised 31.4% of these clinical studies. Moreover, in spite of the increase in the proportion of RCTs in the period from 1999 to 2008, this was insignificant, slow and lower than anticipated, and less encouraging. The difficulties in conducting RCTs in terms of cost, gaining ethical approval, and their time consuming nature may explain this low proportion of published RCTs. It is important to note that both the above studies did not attempt to assess the quality of published papers, but only to classify them subjectively.

Three retrospective observational studies were designed to assess the quality of reporting orthodontic clinical trials. Table 14 summarises the main finding regarding the quality of reporting orthodontic clinical trial in these three studies. Harrison (2003) assessed orthodontic papers that published in three orthodontic journals between 1989 and 1998. The quality evaluation was based on the concealment of allocation, randomisation, double blinding, and the recording of withdrawals and dropouts. She

concluded that in general the quality of reporting of orthodontic clinical trials that were published in three of the leading orthodontic journals was insufficient to allow the readers to assess the validity of the trials and there was a need to improve reporting of clinical trials by strictly following the CONSORT statement. She explained that most of the orthodontic trials failed to minimise the risk of bias because of the lack of double-blinding and inadequate accounting for dropouts. However, an important assumption was also mentioned in the study when she stated that “In orthodontics, it is often very difficult to carry out triple or even double-blind trials, because orthodontic appliances and materials often differ in appearance so that participants and/or clinicians are aware of which intervention any participant is receiving.” (P: 313). However, this is not the case when a study is designed to assess different mouthwashes, toothpaste, or analgesics because in these cases double or triple blinding can be implemented. The solution when it is difficult to apply double or triple-blinding is to hide all the cases identification and record the data by an independent assessor who is unaware of the allocated group. Therefore, when the quality of orthodontic RCTs is to be evaluated, the nature of the study and the appropriate level of blinding of patient, clinician, and assessor that is suitable for each individual study should be considered.

The second study by Flint and Harrison (2010) assessed the compliance of orthodontic clinical trials that published in four orthodontic journals with the CONSORT statement at three periods (1995/1996 pre-CONSORT, 2000/2001 post-CONSORT, and 2005/2006 post revised-CONSORT). The study showed a statistically significant improvement in reporting orthodontic clinical trials after the publication of the CONSORT statement. However, reporting randomisation, blinding, and allocation concealment was insufficient during this period. The authors explained this inadequate reporting due to either the policy of journals that might not mandate the presence of detailed CONSORT statement in submitted papers especially when there is a limited

space within the journal, or, the nature of orthodontic trials might be incompatible with all the guidelines of the CONSORT statement, such as when it is impossible to blind operator and patient to treatment allocation.

Bearn and Alharbi (2015) also reviewed the quality of reporting of orthodontic RCTs published in four orthodontic journals against the guidelines of the CONSORT statement for a period from 2008-2012. They found that the compliance of reporting clinical trials with the CONSORT had increased from 47.8% in 2008 to 56.3% in 2012 but still not adequate. RCTs were few in number representing less than 5% of overall published articles in orthodontic journals. The findings of Flint and Harrison (2010) and Bearn and Alharbi (2015) agree with Plint et al. (2006) who found in their systematic review that adopting the CONSORT guidelines correlated with an improvement in reporting RCTs.

The implications of poor quality orthodontic RCTs can affect the quality of systematic reviews that rely on data derived from several RCTs and unless strict rules are followed to reduce the influence of poor quality trials on subsequent meta-analysis, a substantial amount of bias in the estimation of treatment effect will result. This mandates clear reporting of all details of the materials and methods used in an individual clinical trial, since this will allow the reviewer to determine if any important detail is omitted in order to make a valid judgment whether or not to include the trial in a meta-analysis (Moher et al., 1998; Harrison, 2003).

Pandis et al. (2011) emphasised the importance of sample size calculation and trial design in orthodontic clinical trials. They reported that a sample size calculation should weigh up the scientific validity and feasibility of the study. Additionally, clinical trials with low sample sizes might be considered unethical, wasteful of time and resources, and ultimately do not provide reliable clinical results.

2.4.10 Summary

RCT is the study design of choice when the effectiveness of treatment is to be investigated (Gibson and Harrison, 2011; Pandis, 2011). Several factors can enhance the quality of the RCT and reduce the contribution of bias, such as adequately informed and consented patients, clear inclusion and exclusion criteria, random selection of participants, random allocation to treatment, stratified randomisation, blinding, adequate sample size calculation and accommodation for any expected dropouts throughout the trial, accounting for any excluded or lost data during the trial, and following the CONSORT guidelines rigorously.

A systematic review of multiple RCTs with meta-analysis represents the highest level of evidence in the hierarchy of studies (Pandis, 2011; Jacobs et al., 2013). It has been shown from this review and from systematic reviews that orthodontics is deficient with respect to robust prospective RCTs (Bollen, 2008; Fleming and DiBiase, 2008). Therefore, orthodontic field requires a greater number of well-designed RCTs to be undertaken to provide reliable evidences on the effects of orthodontic treatment.

The benefits of well-designed high quality RCTs may justify the difficulties associated with undertaking this type of study (El-Angbawi, 2013).

Table 14: Findings of three studies about quality reporting of orthodontic clinical trials

Author	Journals Investigated	Period	Finding
Harrison (2003)	• American Journal of Orthodontics and Dentofacial Orthopedics • British Journal of Orthodontics • European Journal of Orthodontics	• 1989-1998	• 155/2407 clinical trials were found representing 6.4% of all the published papers in these journals. 54.8% were RCTs and 45.2% were CCTs • 36.8% of the trials had an appropriate level of blinding • 6.5% of the trials were double-blinded • 2.6% of the trials were adequately concealed • 54.8% of the trials were randomised • The type of randomisation was regarded as appropriate in 50.3% of the trials • 28.4% of the trials described the withdrawals and dropouts • Only one trial (0.6%) had a low risk of bias (all quality criteria were met) • 11% of the trials had a moderate risk of bias (one or more criteria were partially met) • 88.4% of the trials had a high risk of bias (one or more criteria were not met)
Flint and Harrison (2010)	• American Journal of Orthodontics and Dentofacial Orthopedics • The Angle Orthodontist • European Journal of Orthodontics • Journal of Orthodontics	• 1995/1996 pre-CONSORT • 2000/2001 post-CONSORT • 2005/2006 post revised-CONSORT	• 151 clinical trials were included in the study. 65.6% were RCTs and 34.4% were CCTs • 5.3% of the trials reported the method of randomisation adequately • 14.3% of the trials described blinding adequately • 1.3% of the trials reported allocation concealment adequately • CONSORT guidelines significantly improve reporting of clinical trials
Bearn and Alharbi (2015)	• American Journal of Orthodontics and Dentofacial Orthopedics • The Angle Orthodontist • European Journal of Orthodontics • Journal of Orthodontics	• 2008-2012	• 151/3335 clinical trials were identified representing 4.6% of all the published papers in these journals. • Compliance with CONSORT guidelines had increased from 2008 to 2012 • 7.9% of the trials reported the method of randomisation adequately. 35.8% had inadequate report of randomisation and 56.3% did not contain details of randomisation

CHAPTER 3: DEVELOPMENTAL STUDIES

3.1 QUESTIONNAIRE VALIDATION STUDY

3.1.1 Introduction

A questionnaire is a data collection medium for recording information from the population of interest either in a written form or through a structured interview. Its content should be well organised and structured and in a logical order, so that the questions are easily understood, otherwise poor responses will be recorded and the results would be misleading or irrelevant. Similarly, each question in the questionnaire should be asked in exactly the same way for different participants, if not, it will be difficult to interpret the answers. There are different ways to obtain participants' responses in a questionnaire, such as a face to face interview, a telephone interview, or a questionnaire that is self-completed by the participants, which could be sent to them either by mail or via the internet (Brace, 2008; Sue and Ritter, 2008). Researchers can expect that respondents will not always provide completely accurate information, so the questionnaire should be designed in a way that helps the respondents to provide as good information as possible. Moreover, the questionnaire should not be constructed to support a specific idea, but the researcher has to be as objective as possible to produce the best measuring tool (Brace, 2008). Clinical researchers mainly depend on objective measures for their assessments, such as laboratory tests, tissue diagnosis, etc. but, in the past few decades, more concern has been highlighted about the impact of new drugs and new treatment procedures on patients' quality of life, expectations, and experiences. Consequently, reliable and valid scales that assess these subjective states are required (Steiner and Norman, 2008). Since this study is about validation of three existing questionnaires, the review will be focused on the validation of questionnaires.

3.1.2 Questionnaire Validation

Questionnaire validity is the ability of the questionnaire to address its objectives (i.e. whether or not it measures what it is intended to measure) (Shultz and Whitney, 2005; Steiner and Norman, 2008). Validation of questionnaires in clinical research may refer to the process by which the questionnaire is assessed for the robustness of data collection. Since it usually evaluates subjective measures, validating questionnaires is somewhat tricky as they might be influenced by a range of factors that are difficult to control (Howard, 2006). Generally, two main approaches are used to assess validity (Steiner and Norman, 2008):

- ***When other measures exist:*** the questionnaire or measures are compared with an already existing measure or scale for a similar trait. Good validity is obtained when a strong correlation is found between the two measures. Such an approach is easily applied, however, justification may be required to develop a new measure when there is a previously existing one unless it will be cheaper or simpler;
- ***When no other measures exist:*** these questionnaires are more justifiable since they are developed for the first time. In this case, a hypothesis should be constructed before investigating the relationship between this hypothesis and the measure being used. A strong correlation means that the hypothesis and the measure are sound; alternatively, a weak or no relationship indicates that a fault may be present in one of them.

It is necessary to test out any newly written questionnaire or even an old questionnaire that has been modified for a new study before use. This can be achieved through a pilot study or by observing, revising and applying the questionnaire until all the observers and the respondents are satisfied that this is the best version for the condition under investigation (Brace, 2008).

3.1.2.1 Types of Validity

In the past, specifically before the 1950s, the term validation was used to indicate the predictability of the results of a test/index and the accordance with the performance of the task under investigation. This is called *criterion validity* and it is applicable in areas where standard criteria are present (Kane, 2001). In other fields, the test should be checked so that its content is fully addressed and any irrelevant items are eliminated. In such cases, the content of the test is evaluated in order to be intrinsically valid. This is now known as *content validity* and might be applied in achievement testing to make sure that the contents of the test are suitable for persons who are to be assessed. However, there are some domains in which neither standardised criteria are available nor is content validity suitable, such as in psychological feelings and pathological conditions including anxiety and depression (Messick, 1989). To solve this problem, Cronbach and Meehl in 1955 introduced the term *construct validity*. This form of validity is based on testing a hypothesis which is derived from the underlying construct of the topic under investigation (e.g. anxiety). For example, a hypothesis could state that "anxious people have a lower pain threshold than non-anxious people". The study should be designed as per the prediction if the theory is correct and if the test is valid. Since many hypotheses might be derived from the construct of the theory, construct validity is considered as a continuous task (Steiner and Norman, 2008). From the above, it can be concluded that validity can be generally divided into the "three Cs" of *content validity, criterion validity* and *construct validity*. Subdivisions of these types also exist (Messick, 1980; Landy, 1986; Steiner and Norman, 2008), such as "face validity" which can be related to content validity, "concurrent" and "predictive" validity which are subdivisions of criterion validity, while "convergent" and "discriminant" validity are subdivisions of construct validity.

A scale or questionnaire cannot be fully validated because each type of validity is unique and a questionnaire might have one kind of validation but not the other, so it can be validated for a certain patient population under certain conditions. For example, it is not suitable to use a questionnaire for a particular type of cancer such as lymphoma for another type such as melanoma, unless the questionnaire has been validated in a way that it can be applied to cancer patients generally. Similarly, applying the scale on a population from a different ethnic group or with a different level of education or under various circumstances may disturb the validity (Howard, 2006; Steiner and Norman, 2008). Validity of the questionnaire can also be affected by the individuals who manage it. Therefore, it must be administered by well-trained individuals and in the right setting (Howard, 2006).

If the questionnaire needs to be translated to other languages, the new version should be checked so that it is as consistent and predictable as the original version, because due to trans-cultural differences, some of the contents of the questionnaire might not be understandable across cultures and may require alteration (Damato et al., 2005; Howard, 2006).

As this study evaluates the content validity of three questionnaires, the review will be focused on content validity, face validity, and reliability.

3.1.2.1.1 Content Validity

Content validation is often a very important method when developing a new questionnaire. It can be defined as “the degree to which elements of an assessment instrument are relevant to and representative of the targeted construct for a particular assessment purpose” (Haynes et al., 1995: 238). It can also be defined as “the degree to which an instrument has an appropriate sample of items for the construct being measured” (Polit and Beck, 2004: 423). Content validity is undertaken only by experts

to ascertain whether the content of the questionnaire is appropriate and relevant to the purpose of the study or if particular items should be omitted or additional items and statements are required (Lynn, 1986; Polit and Beck, 2004; Shultz and Whitney, 2005).

3.1.2.1.1.1 Content Validation Stages

Lynn (1986) identified two stages for determination of content validity:

Stage I: Developmental stage

- ***Step 1:*** identification of full content domain. This can be done following a comprehensive literature review, seeking expert opinions, population sampling or qualitative research.
- ***Step 2:*** item generation.
- ***Step 3:*** instrument formation in a usable form.

Stage II: Judgement-quantification stage

- ***Step 4:*** evaluation of content validity of items.
- ***Step 5:*** evaluation of content validity of the instrument.

To undertake content validity, a panel consisting of a suitable number of experts is asked to determine the relevance of the individual items and the scale as a whole to the underlying construct (what the questionnaire intends to measure). This is done using a content validity index (CVI). In addition to this quantitative method, a qualitative evaluation by experts is also necessary for content validation. According to the results of the validation, items can be retained, eliminated, or reworded with further revision as required. If an instrument has already been created but not tested, the content validity determination can be applied after skipping steps 2 and 3 (Lynn, 1986).

3.1.2.1.1.2 The Content Validity Index (CVI)

The content validity index is the proportion of items in an instrument that is considered relevant to the construct being measured by the content expert raters (Waltz et al., 2005; Polit and Beck, 2006). There are two types of CVI; the content validity of the individual items or the item-level CVI (I-CVI) and the content validity of the overall scale or the scale-level CVI (S-CVI). In order to determine item acceptability including standard error of proportion, Lynn (1986) suggested that a panel of reviewers consisting of a minimum of three experts is required to assess content validity. The maximum number of experts has not been determined but is unlikely to be greater than ten experts. Each expert in this panel would independently rate each individual item within the scale to determine its relevance to the underlying construct using a 4-point Likert scale (1 = not relevant, 2 = somewhat relevant, 3 = relevant, 4 = very relevant). The item level CVI (I-CVI) represents the number of content experts rating each item 3 or 4 (relevant and very relevant) divided by the total number of experts (the proportion of experts who rated each item as content valid). Therefore, the 4-point ordinal scale is reduced into a dichotomy of a 2-point nominal scale of “relevant” and “not relevant” during the analysis of the expert rating. The accepted level of I-CVI should be 1.00 when the number of experts/reviewers totals five or less (i.e. all the experts are rating 3 or 4). When the number of reviewers is six or greater, the recommended I-CVI should not be lower than 0.78. For example, one of the six experts could rate “not relevant” (I-CVI= 0.83) or two not relevant ratings from nine expert ratings (I-CVI= 0.78) can also be accepted (Table 15). The S-CVI (or S-CVI/Ave) is the proportion of total items rated as “content valid”. It can also be obtained by averaging the I-CVIs for all items on the scale (summing them and dividing by the total number of items) and this method is considered by Polit and Beck (2006) as the best way of measuring the S-CVI because it focuses on the average item quality. The average congruency percentage for the S-CVI,

as recommended by Waltz et al. (2005), should be 0.90 (Lynn, 1986; Waltz et al., 2005; Polit and Beck, 2006; Polit et al., 2007; Parsian and Trish Dunning, 2009; Cannon and Hubley, 2014; Wang et al., 2013; Zamanzadeh et al., 2015; Larsson et al., 2015).

Table 15: Proportion of experts (above the line) whose endorsement is required to establish content validity beyond the 0.05 level of significance (Lynn, 1986)

Number of experts	Number of experts endorsing item or instrument as content valid								
	2	3	4	5	6	7	8	9	10
2	1.00								
3	0.67	1.00							
4	0.50	0.75	1.00						
5	0.40	0.60	0.80	1.00					
6	0.33	0.50	0.67	0.83	1.00				
7	0.29	0.43	0.57	0.71	0.86	1.00			
8	0.25	0.38	0.50	0.63	0.75	0.88	1.00		
9	0.22	0.33	0.44	0.56	0.67	0.78	0.89	1.00	
10	0.20	0.30	0.40	0.50	0.60	0.70	0.80	0.90	1.00

The CVI as a method of calculating content validity has many advantages. For example, it is easily understood, easy to calculate and communicate, provides information at both item level and scale level, and focuses on consensus rather than consistency estimation. The latter is important because consistency analyses, such as the alpha coefficient could have a high value even in cases where content validity agreement is low, because these measures focus on the agreement across the experts in their rating order, while consensus measures focus on the agreement in relevance rating for the items which makes them more suitable to reflect validity (Polit et al., 2007). The main drawback of the CVI as a proportion of agreement is that it might be affected by a chance agreement. Lynn (1986) adjusted this by incorporating a standard error of proportion and set levels for accepted I-CVI according to the number of experts. However, the argument continued regarding the suitability of the CVI and this promoted Wynd et al. (2003) to compare between both CVI and multi-rater kappa coefficient (as a consensus measure

that adjusts for chance agreement). They concluded that kappa analysis is a suitable supplement (if not a substitute) for the CVI.

In 2007, an influential analysis by Polit et al. solved this argument. The value of CVI had been linked to that of kappa which was adjusted for the chance of agreement on relevance and then different scenarios were used for different numbers of experts with varying relevance rating of items. The results supported Lynn's guidelines and it was concluded that wherever the I-CVI value is greater than 0.78 it would fall within an excellent range of kappa (0.75 or higher) regardless of the number of experts. For ten experts or more, the same results would be obtained when the I-CVI is greater than 0.75. These findings were recently supported by Larsson et al. (2015) and Zamanzadeh et al. (2015) who found similar results in their studies. The only disagreement between Lynn (1986) and Polit et al. (2007) studies was when Polit et al. (2007) reported that the total agreement among experts is only required in case of three or four experts, not with fewer than six as Lynn mentioned.

The uniqueness of content validity compared to other types of validation is that it does not depend on the results of the test/scale or its outcomes such as performance difference between people. Instead, it depends on the professional judgment on the entire contents of the test, although the content itself may also affect the inferences that can be derived from the test either directly or indirectly (Messick, 1989; Steiner and Norman, 2008). There is a positive correlation between the content validity and what can be determined from the test or the study. Therefore, the higher the content validity of the test, the wider the range of conclusions that can be derived (Steiner and Norman, 2008).

Lynn (1986), Haynes et al. (1995), Rubio et al. (2003) and Polit et al. (2007) emphasised the importance of further evaluation following initial content validation.

McCain (1984) and Lynn (1986) suggested that if the questionnaire required a second round of validation with the same reviewers, this should be done after a period of time not less than ten days from the first assessment.

3.1.2.1.2 Face Validity

This type of validity is considered as the simplest as well as the weakest form of validity and is sometimes confused with content validity. However, it is more superficial and does not require any quantitative methods. It measures the appropriateness of the content of the questionnaire, which can be regarded as "on the face of it", by evaluating its appearance in terms of relevance to the construct, clarity of the language and readability, style and formatting consistency and feasibility. Experts need only to look at the questionnaire as a whole and its individual items and determine whether it measures what it should measure and assesses the preferred qualities. Respondents can also evaluate the questionnaire using a face validity form or evaluation form which can be developed to facilitate the assessment procedure. Each question or individual item should be checked to ensure that the words, grammar and layout are simple, understandable, and in logical order (effectively capturing the topic under investigation). It is a subjective assessment and rarely any empirical methods are used (Lynn, 1986; DeVon et al., 2007; Steiner and Norman, 2008; Parsian and Trish Dunning, 2009; Polikandrioti et al., 2011; Sangoseni, 2013; Verial, 2014; Najarkolaei et al., 2014; Zamanzadeh et al., 2015; Trochim et al., 2015). In some studies, face validity has relied solely on experts (Iwasaki et al., 2013, Sangoseni et al., 2013), or respondents (Sayers and Newton, 2006; Parsian and Trisha Dunning, 2009; Polikandrioti et al., 2011; Najarkolaei et al., 2014), whereas in other studies, both experts and respondents have been included (Zamanzadeh et al., 2015).

The assessment procedure can be attained through interviews with respondents, observing them while completing draft versions of questionnaires. After that, a face validity form can be utilised to gather the responses and test the appropriateness of the questionnaire using scales such as a Likert scale of 1-4: 1 = strongly disagree, 2 = disagree, 3 = agree, and 4 = strongly agree, (Parsian and Trish Dunning, 2009).

The main difference between face validation and content validation is that any individual can participate in face validation of a questionnaire, whereas content validation should be performed by relevant professionals or experts only. Guilford (1954) termed this approach of validation (face and content) as “validity by assumption”, which means that the instrument was assumed to measure what it was intended to measure (Steiner and Norman, 2008; Polikandrioti et al., 2011; Verial, 2014).

Occasionally, face and content validation should be approached with caution; this may include questions in sensitive areas such as those related to child abuse or excessive alcohol consumption, because they may appear to have face validity however they will not reveal an accurate response. Such questions may have a weak relationship to the underlying attitude and consequently, poor face and content validity will result. In such cases, it may be necessary to avoid straightforward questions in order to provide, at least, the minimum standard of the face and content validity (Steiner and Norman, 2008).

3.1.3 Questionnaire Reliability

Questionnaire reliability is a process in which the questionnaire is reviewed to determine reproducibility (repeatability) and internal consistency. Therefore, the basic idea is to obtain stability of the questionnaire when it is administered on different occasions or by different researchers and to ensure that the items of the questionnaire are well fitted conceptually (DeVon et al., 2007; Steiner and Norman, 2008). Although reliability is important for a questionnaire/instrument, it does not reflect validity, because an instrument could be reliable but not valid (DeVon et al., 2007). There are two main forms to test reliability.

3.1.3.1 Internal Consistency

This measures the correlation of the individual items of the questionnaire and how well they are matched together (DeVon et al., 2007). For example, if a questionnaire consists of a number of items that measure the social behaviour of the individual, such as 'Do you have friends?', 'Do you visit your relatives?', 'Do you participate in social events?', we can expect a good correlation of the scores of each item with the scores of other items since they are dealing with the same underlying aspect. Internal consistency represents the average of the correlations among all the items in the questionnaire and it can be calculated by tests such as *Cronbach alpha*, *Kuder-Richardson*, or *Split halves* (Steiner and Norman, 2008; Trochim et al., 2015).

3.1.3.2 Stability

This is the capability of the questionnaire to produce the same result when run on different occasions (reproducibility). Intra-observer reliability is the degree of agreement between observations undertaken by the same observer on two different occasions. Inter-observer reliability is the degree of agreement among different observers. Test-retest reliability is measured when the observations are on two

occasions separated by some interval of time, postulating that no significant change in the construct under study will happen between the two observation time periods. The high correlation between the scores of the two observations reflects the stability of the instrument (Haladyna, 1999; DeVon et al., 2007; Steiner and Norman, 2008; Parsian and Trish Dunning, 2009; Trochim et al., 2015). If the instrument designed to measure changes within patients during a period of time, it should be tested for responsiveness.

Responsiveness: this refers to an instrument's ability to detect change. If a treatment results in an important difference, the instrument should be able to detect even the small difference. Responsiveness will be directly related to the magnitude of the difference in scores in patients who have improved or deteriorated and the extent to which patients who have not changed provide more or less the same scores (Guyatt et al., 1993).

Reliability represents the ratio of the variability between subjects to the total variability in the scores. Therefore, it is expressed as a number between 0 and 1, where 0 means no reliability and 1 indicates perfect reliability (Steiner and Norman, 2008). Generally, Cronbach alpha coefficient (for internal consistency) and intraclass correlation coefficient (for test-retest reliability) are considered acceptable with values ≥ 0.70 (DeVon et al., 2007; Momayyezi et al., 2015; Hanson et al., 2016).

3.1.4 Validity and Reliability of Patient-Related Outcomes Used in Orthodontics

Evidence shows that patient satisfaction with treatment is necessary for compliance as well as to increase adherence and interest in treatment. For this reason, there is an increasing interest in patient satisfaction with different aspects of dental care (Pascoe, 1983; Ball, 1996).

Although some patient satisfaction measures have been developed for the dental subspecialties (Boerrigter et al., 1995), valid scales are still required to measure patient satisfaction in orthodontics. The European orthodontic community has developed a measure of orthodontic treatment satisfaction and emphasised the importance of patient satisfaction as part of the quality of care. However, validation is still required for such scales (Bennett et al., 2001).

Evaluating patient satisfaction with orthodontic treatment is a complicated task, especially when accomplished by a single and simple question at the end of the treatment such as “are you satisfied with your treatment results?”. Since orthodontic treatment is multidimensional, some patients or parents when asked such a question may express their feeling of satisfaction, but they may be dissatisfied with other specific aspects of the treatment. Consequently, Bennett et al. (2001) mentioned that designing and validating a questionnaire that covers the different aspects of orthodontic treatment was necessary.

Bennett et al. (1997) designed and tested a questionnaire to identify the expectations of parents and orthodontists in relation to orthodontic treatment. In an attempt to assess at least three possible dimensions of parental satisfaction with their child’s orthodontic treatment, Bennett et al. in 2001 developed a questionnaire that provides information about how parents construct their experiences with their child’s treatment. Both these

questionnaires shared similar features. Preliminary validity was only relied upon by assessing the relationships between demographic variables and subscale scores (Bennett et al., 1997) and between parent satisfaction and visible orthodontic outcome (Bennett et al., 2001). This suggests that a comprehensive validity assessment was required. Cronbach alpha analysis in both studies revealed adequate reliability for the questionnaires. However, the sample was not large enough to represent all subjects seeking orthodontic treatment at private clinics or teaching institutes. Moreover, data collection did not follow a uniform manner in these studies.

A condition-specific questionnaire was developed by Klages et al. (2006) to assess the psychological impact of dental aesthetics in young adults “Psychological Impact of Dental Aesthetics Questionnaire” (PIDAQ). It included items from the Orthognathic Quality of Life Questionnaire (Cunningham et al., 2000 and 2002). The PIDAQ was validated in terms of content and criterion-related validity and it met the factorial stability using a principal component analysis and consistency reliability using Cronbach alpha test which ranged from 0.85-0.91. No detailed information about the content validity was provided in the study. Furthermore, other limitations were also detected about the PIDAQ, such as limited generalisability, unproven suitability for different age groups, and as it is condition-specific it might not be considered as a comprehensive questionnaire for orthodontic patients.

The Child Perception Questionnaire (CPQ_{11-14}), was originally developed and assessed for validity and reliability by Jokovic et al. in 2002 to measure the impact of oral and oro-facial conditions on OHRQoL for children aged 11 to 14 years. This questionnaire was also evaluated for validity and reliability as a measure of OHRQoL for orthodontic child patients in the UK by different studies (Kok et al., 2004; Marshman et al., 2005; O’Brien et al., 2006; O’Brien et al., 2007; Marshman et al., 2010) and in Saudi Arabia

by Brown and Al-Khayal (2006). Some concerns were reported about the the CPQ in terms of face and content validity, ability to discriminate between different types of malocclusions or other oral conditions, and the length of the questionnaire (Kok et al., 2004; Marshman et al., 2005; Brown and Al-Khayal, 2006; O'Brien et al., 2007; Marshman et al., 2010). This was because the CPQ was not developed specifically to assess the impact of orthodontic problems. On the other hand, O'Brien et al. (2006) reported that the CPQ_{11-14} has adequate validity and reliability and considered it as a useful measure for orthodontic trials. All the instrument items measure the same construct (oral health-related quality of life). Additionally, it has validity to assess the effect of malocclusion on the child's OHRQoL. These results supported the concepts described by the developers of this questionnaire.

Since the effectiveness and quality of orthodontic treatment are closely related to patient expectations, a valid and reliable scale that measures patient expectations is also required. For this reason, Sayers and Newton (2006) developed their questionnaire and tested it for validity and reliability because most of the previous studies investigating patient expectation have not been evaluated for their validity and reliability. Sayers and Newton (2006) included two phases for this development and validation. The first phase included open-ended questions in a semi-structured qualitative interview with patients and their parents (conducted separately). Information from these meetings was used to construct the questionnaire. The second phase included completion of the questionnaire by five new patients and their parents and finally, the questionnaire was distributed to the whole study sample. Test-retest reliability was analysed by Spearman rank correlation coefficient, while Cronbach alpha evaluated internal consistency reliability. Face validity was assessed by subjective evaluation and relevance of the questionnaire to the participants. This study produced a reliable and valid measure of orthodontic expectations for 12-14 year-old UK children and their parents. However, reliability and

validity are at risk from several factors. For instance, reliability outcomes may be limited because the data for the patients and parents were summed together due to the small sample size, the use of Spearman rank correlation coefficient to measure the reliability is not always accepted, and as the authors mentioned, the results could be affected by different forms of biases and errors. Moreover, face validity is a weak form of validating the content of any questionnaire when compared with content validity which was not implemented in the study.

Mandall et al. in 2006a developed a questionnaire to measure the impact of fixed orthodontic appliances on daily life of orthodontic patients (children), using standard qualitative methods. It consists of subscales relating to aesthetic impact, functional limitation, dietary impact, oral hygiene impact, maintenance impact, physical impact, social impact, time constraints, and travel cost inconvenience. Reliability of the questionnaire was confirmed by both internal consistency (Cronbach alpha) and test-retest reliability (Intraclass correlation coefficient). The authors claimed that the questionnaire has face and content validity basing only on the method of development through patient interviewing and piloting without providing further details and they recommended starting orthodontic treatment as early as possible as the questionnaire revealed that younger patients could adapt more easily to treatment with fixed appliances in terms of reduced impact on daily life (Mandall et al., 2006a).

Feldmann et al. (2007) designed a questionnaire to evaluate adolescent patients' expectations and experiences with orthodontic treatment. The questionnaire was first developed through interviews with patients who had recently completed orthodontic treatment and with parents of adolescent patients in retention. Forty-six items were included from these interviews and from previous questionnaires and they covered: treatment motivation and expectations, pain and discomfort, jaw functional impairment,

and questionnaire face validity. The next step included assessing the reliability of the questionnaire using both internal consistency (Cronbach alpha) and test-retest reliability (Intraclass correlation coefficient and Cohen's kappa). Face validity has also been assessed and the final questionnaire showed adequate face validity and internal consistency with most of its domains have acceptable test-retest reliability. The main limitation of this questionnaire is that it relied solely on face validation to determine the validity.

An instrument assessing the motivating factors and psychological characteristics of adults seeking orthodontic treatment was developed by Pabari et al. (2011). Although the questionnaire was tested for reliability, content, and face validity, the authors simply reported that the content validity was undertaken by experts and face validity was undertaken by experts and patients. No further information was reported regarding how they implemented each method.

Iwasaki et al. in 2013 modified and validated the McGill Pain Questionnaire-Short Form (MPQ-SF) for adolescent orthodontic patients aged 11-17. The modified version of the questionnaire, initially included 15 description items (MMPQ-SF15), was tested on a sample of patients during orthodontic treatment. It was assessed for face validity and additionally, discriminant validity was tested to find out the ability of MMPQ-SF15 to discriminate pain against a visual analogue scale (VAS) indicating the severity of pain. The results showed that the MMPQ-SF15 and eleven of the descriptors were found to be discriminatory for pain, while four descriptors were unable to do so and were consequently eliminated from the questionnaire (which was refined to be MMPQ-SF11). Construct validity of the MMPQ-SF11 was completed after subjecting the data to principal components factor analysis with varimax rotation, while criterion-related validity was measured by correlating the MMPQ-SF15 and MMPQ-SF11 with other

accepted pain measures, including the present pain index (PPI) and VAS scores using Spearman rank correlation coefficients which revealed a strong correlation. Although this study was valuable, limitations have been reported including sample size, gender differences and age appropriateness of the instrument used.

Shahrani et al. (2015) designed a questionnaire to evaluate patient expectations and satisfaction with orthodontic treatment and related services. The questionnaire revealed an acceptable internal consistency with Cronbach alpha (0.77). However, the content of the questionnaire was only tested with face validity without undertaking content validity.

The study by Benson et al. (2016) has confirmed the validity and reliability of the Malocclusion Impact Questionnaire (MIQ) as a condition-specific measure of OHRQoL for young people with malocclusion. The questionnaire achieved good criterion and construct validity as well as good internal consistency and test-retest reliability. Face and content validity were also reported as good, although no data regarding the content validity was presented. The MIQ was developed by Patel et al. (2016) and it still required further evaluation to confirm the generalisability and ability to detect changes over time.

As a conclusion for this review, most of the published studies in the literature have used questionnaires designed for children (with or without help from their parents) using generic OHRQoL questionnaires or modified versions of these. These include the 14-item Oral Health Impact Profile (OHIP and OHIP-14), the Child Perception Questionnaire (CPQ and CPQ_{11-14}), the United Kingdom Oral Health-Related Quality of Life (OHQoL-UK), the Oral Impacts on Daily Performance (OIDP), the Short-Form 36-Item Health Survey (SF-36), Oral Aesthetic Subjective Impact Scale (OASIS), Malocclusion Impact Questionnaire (MIQ), and the Psychosocial Impact of Dental

Aesthetics Questionnaire (PIDAQ). Other specific questionnaires evaluate aesthetics (e.g. the Dental Aesthetic Index) or pain during treatment. These instruments were not originally developed for patients undergoing fixed appliance orthodontic treatment but for the impact of malocclusion or other health issues on quality of life and they may not be directly applicable in orthodontics (O'Brien et al., 1998; Kok et al., 2004; Cunningham and O'Brien, 2007) and so may not address certain aspects of fixed appliance orthodontic treatment. Currently, the impact of orthodontic treatment is usually measured in terms of the improvement of the OHRQoL with little attention to the impact of appliances on treatment.

The questionnaires used in this study were produced by O'Brien et al. (2003) for the evaluation of patient perception and experience with functional appliances. Although the investigators were not aware of the method of development for these questionnaires which may not robust enough, the questionnaires contained comprehensive items about treatment and since fixed and functional appliance orthodontic treatment share many aspects it was decided to modify and validate these questionnaires for fixed appliances rather than starting afresh. The questionnaires were used to quantify patient expectations, experiences, and the impact of orthodontic treatment before, during, and after orthodontic treatment with 0.018-inch and 0.022-inch slot bracket systems (pre-adjusted MBT prescription) in the current RCT.

3.1.5 Aims of the Study

This study aims to determine the content validity, face validity, and reliability of the Pre-treatment, Smiles-Better, and Post-treatment Questionnaires to develop a set of validated questionnaires to assess patient perception throughout orthodontic treatment with fixed appliances.

3.1.5.1 Null Hypothesis

The Pre-treatment, Smiles-Better and Post-treatment questionnaires are not valid indices for measuring patient expectation, experience, and satisfaction with fixed appliance orthodontic treatment.

3.1.6 Materials and Methods

3.1.6.1 Validation of the Questionnaires

Content and face validity were undertaken to assess the validity of the Pre-treatment, Smiles-Better, and Post-treatment Questionnaires (Appendix 3, 4, and 5). For each validation test, two rounds were performed as described below.

3.1.6.1.1 First Round of Validation

3.1.6.1.1.1 Content Validity

A quota sample of ten Specialist Orthodontists was invited to participate in an expert panel for content validity. They were international, practiced in a variety of geographical regions and settings with different levels of experience. Each expert/reviewer received copies of the three questionnaires along with instructions and the three constructs with their domains. The experts were asked to independently determine the relevance of each questionnaire item to the relevant underlying construct using a 4-point Likert scale (1 = not relevant, 2 = somewhat relevant, 3 = relevant, 4 = very relevant) (Appendix 6). The constructs were created after a comprehensive review of the literature and expert consultation as suggested by Lynn (1986) and Mastaglia et al. (2003). The constructs are:

- Pre-treatment Questionnaire:

"Patient expectations of treatment with fixed orthodontic appliances"

- Smiles-Better Questionnaire:

"Patient experience during active treatment with fixed orthodontic appliances"

- Post-treatment Questionnaire:

"Having undergone orthodontic treatment with fixed orthodontic appliances, this will have had an impact on the patient's dental health status and lifestyle"

The following domains were considered:

- Relevance for orthodontic patients
- Patient perception/experience with orthodontic treatment
- Aesthetic aspects of orthodontic treatment
- Social aspects of orthodontic treatment
- Psychological aspects of orthodontic treatment
- Oral health aspects of orthodontic treatment
- Functional aspects of orthodontic treatment

Content validity was assessed using the content validity index (CVI), which is the proportion of items in the questionnaire considered relevant to the construct by the content expert raters (Waltz et al., 2005; Polit and Beck, 2006). Both the item-level CVI (I-CVI) and the content validity index of the overall scale or the scale-level CVI (S-CVI) were calculated according to Lynn's method (1986) [this method was also discussed in detail by Polit and Beck (2006) and Polit et al. (2007)]. The item level CVI (I-CVI) was calculated as the number of content experts who rated each item 3 or 4 (relevant and very relevant) divided by the total number of experts (the proportion of experts who rated each item as content valid). Therefore, the 4-point ordinal scale was dichotomised into a 2-point nominal scale of "relevant" and "not relevant". Since the number of expert raters in this study was ten, a minimum of eight experts rating 3 or 4 were needed to determine the item to be content valid and therefore retained in the questionnaire (I-CVI $\geq$ 0.80 at $P < 0.05$) i.e. any item with I-CVI below 0.80 was removed from the questionnaire. The S-CVI (or S-CVI/Ave) was calculated as the proportion of total items rated as "content valid". This was also obtained by averaging the I-CVIs for all items on the scale (Polit and Beck, 2006). For the overall questionnaire to be valid the minimum accepted level of S-CVI/Ave was 0.90 as recommended by Waltz et al. (2005).

3.1.6.1.1.2 Face Validity

Since there is no specific method used routinely in the literature to evaluate face validity, this was evaluated in this study by subjective reviewing of the questionnaire "on the face of it" in terms of appropriateness of the content, clarity of the language and readability, brevity, and consistency of the style and formatting. Both professionals and patients/respondents were asked to participate in face validation of the three questionnaires. Patients were considered as "experiential experts" (Schilling et al., 2007)

3.1.6.1.1.2.1 Face Validity with Professionals

The professional panel consisted of eleven members (seven Specialist Orthodontists and four orthodontic postgraduate students) of varying nationality and experience. Each member of the panel was asked to review the questionnaires to assess the appropriateness for patients treated with fixed orthodontic appliances as well as the clarity of the phrases, consistency of the style and formatting, completeness, and order of the questions. The professional panel recorded their data on feedback forms created for this purpose using a 4-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = agree, 4 = strongly agree) (Appendix 7, 8, 9, and 10). The feedback form also offered an opportunity for qualitative feedback from the reviewer.

3.1.6.1.1.2.2 Face Validity with Respondents

The respondent panel consisted of a group of 20 patients, who consented to participate in this anonymous review and were provided with a copy of each questionnaire and the respective (respondent) feedback form along with the instructions and the purpose of this review (Appendix 11, 12, and 13). They were selected from the Orthodontic Clinic at Dundee Dental Hospital and School using a non-random quota sampling method from patients of both genders scheduled for fixed appliance treatment from a variety of age groups (12 years and above) with no need for adjunctive treatment (not from the clinical

trial sample). The patients were asked to review the content of the questionnaires thoroughly while they were sitting in the waiting room. Then they reported their feedback to determine whether the questionnaires were relevant for orthodontic patients, clear and easily understood, easy to follow and in a logical order, and if important aspects were not addressed. Qualitative evaluation was also possible within the feedback forms via the final question which was an open-ended question. The feedback proformas followed a systematic layout and were designed by the study authors and then reviewed by an independent reviewer before use.

3.1.6.1.2 Questionnaire Modification

The questionnaires were then modified by excluding the non-valid items (those with I-CVI < 0.80) from the content validity with other items modified and additional items included according to feedback from the face validity panels (two items were added for the Pre-treatment and three items for the Post-treatment Questionnaires).

3.1.6.1.3 Second Round of Validation

The second round of validation started with the modified questionnaires. The period between the two assessments was approximately two months.

3.1.6.1.3.1 Content Validity

The same procedure carried out in the first round was also performed in the second round of validation. A panel of seven experts from the University of Dundee (six of whom participated in the first round of validation), were selected and asked to participate in this round of validation. Each expert/reviewer received copies of the three questionnaires along with an introductory cover letter explaining the aim of the study and providing the three constructs with their domains. The experts were asked to independently rate the relevance of each item in the questionnaires to the underlying construct (Appendix 14).

3.1.6.1.3.1.1 Face Validity with Respondents

This round included a further non-random quota sample of ten patients from the Orthodontic Clinic at Dundee Dental Hospital and School, who did not participate in the first round of validation, but with similar selection criteria. They consented to participate in this part of the study and then the researcher provided each patient with a copy of each questionnaire and the respective feedback form as well as the instructions and the purpose of this component of the study. The procedure was similar to the first round of validation. The patients were asked to review and provide their feedback about the questionnaires in terms of feasibility, clarity, relevance for orthodontic patients, and whether or not important aspects were missing.

3.1.6.2 Reliability

The validated version of the Smiles-Better Questionnaire and the valid (retained) items of the Pre-treatment and Post-treatment Questionnaires were assessed for internal consistency reliability to determine the strength of inter-item correlations. Due to the change in the environment/situation of patients because of treatment, it was not possible to test the questionnaires for repeatability (test-retest).

Thirty-three patients were randomly chosen from the Orthodontic Clinic at Dundee Dental Hospital and School were invited to complete the validated version of the Smiles-Better Questionnaire (Orthodontic Experience Questionnaire) approximately six months from the start of treatment. For the Pre-treatment and Post-treatment Questionnaires, data were obtained from 35 randomly chosen participants who previously completed the questionnaires in the current RCT. In order to identify the number of subscales with items that were primarily related to each other within the Orthodontic Experience Questionnaire, a factor analysis using principal components analysis with varimax rotation was undertaken.

3.1.6.3 Statistical Analyses

Content validity was determined according to the values of I-CVI and S-CVI/Ave using a spreadsheet (Excel, Microsoft, Washington, USA). Regarding *face validity*, a questionnaire is only assessed as valid when it "looks like" a valid measure of the construct with an adequate percentage of each parameter in the feedback form (> 70% was used in the absence of published levels as this is generally accepted as an adequate agreement in agreement tests).

The Cronbach alpha correlation coefficient was used for assessing *internal consistency reliability* (Trochim et al., 2015). The acceptable value was considered as ≥ 0.70 (Momayyezi et al., 2015; Hanson et al., 2016). Factor analysis using principal components analysis with varimax rotation was undertaken to identify the number of underlying subscales. Statistical Package for Social Sciences for Windows, version 22.0 (SPSS Inc., Chicago, Illinois, USA) was used for Cronbach alpha and factor analysis.

3.1.7 Results

3.1.7.1 Before (Pre) Treatment Questionnaire

3.1.7.1.1 First Round of Validation

3.1.7.1.1.1 Content Validity

Expert rating showed that only 12 items were content valid and relevant to the construct under investigation (I-CVI ≥ 0.80), while 11 items were non-valid (I-CVI < 0.80). The CVI for the overall questionnaire (S-CVI/Ave) was 0.60, which is below the threshold for questionnaire validity (0.90). The non-valid items were therefore removed from the questionnaire. Table 16 summarises the result of content validity for the Pre-treatment Questionnaire.

3.1.7.1.1.2 Face Validity with Professionals

The results revealed that the Pre-treatment Questionnaire had near perfect agreement for face validity (overall agreement = 97.52%). All the 11 professional panel members believed that the questionnaire was appropriate and relevant for pre-treatment orthodontic patient expectations, had a consistent format and style, covered the major aesthetic, social and functional aspects, and could be used as a “Pre-treatment Questionnaire for Orthodontic Patients”. The questionnaire was reported to be easily understood and to cover the psychological and oral health aspects adequately by 10 of the 11 professionals (Table 17). However, some recommendations were provided by the professionals and 2 of 11 identified some aspects that were not included. These are illustrated along with the patients’ recommendations in Table 18.

3.1.7.1.1.3 Face Validity with Respondents

All the 20 patients rated the questionnaire as having perfect face validity (overall agreement = 100%) because it had appropriate content for patients before orthodontic treatment, had clear and easily understood phrases, was easy to follow and in a logical

order, and was consistent in terms of style and layout (Table 17). Two patients had recommendations for further improvement for the questionnaire (Table 18).

Table 16: Content validity results for each item in the Pre-treatment Questionnaire (first round)

Validity	N	Item	I-CVI
Valid Items	1	To make my smile nicer	**1.00**
	2	To make my teeth look nicer	**1.00**
	3	To make my face look better	**0.80**
	4	To make me look better	**1.00**
	5	To feel more confident	**0.90**
	6	To make me feel better about myself	**1.00**
	7	To make me feel better about going out	**0.80**
	8	To help my top and bottom teeth fit together	**0.80**
	9	To help my front teeth fit together	**0.90**
	10	To help my back teeth fit together	**0.80**
	11	To help me chew food better	**0.80**
	12	To make it easier to bite into food	**0.80**
Non Valid Items	1	To make my family happy	**0.40**
	2	To help me with my school work	**0.00**
	3	To help my breathing	**0.10**
	4	To help me speak more clearly	**0.40**
	5	To keep my gums healthy	**0.60**
	6	To make me healthier	**0.20**
	7	To keep me from losing teeth in the future	**0.40**
	8	To help me make friends	**0.30**
	9	To keep my jaw joints healthy	**0.20**
	10	To help keep my jaw joint from clicking	**0.30**
	11	To make it easier to get on with people	**0.40**
S-CVI/Ave			**0.60**

Table 17: Face validity results with professionals and patients for the Pre-treatment Questionnaire (first round)

Panel	Domains	% of Validity
Professionals (N = 11)	The content of the questionnaire is appropriate as a pre-treatment patient expectation index	**100%**
	The content of the questionnaire is appropriate and relevant for orthodontic patients	**100%**
	The phrases of the questionnaire are easily understood	**90.91%**
	The questionnaire has consistent format and style	**100%**
	The questionnaire covers the most important aspects of pre-treatment patient perception	**100%**
	The questionnaire covers aesthetic aspects adequately	**100%**
	The questionnaire covers social aspects adequately	**100%**
	The questionnaire covers psychological aspects adequately	**90.91%**
	The questionnaire covers oral health aspects adequately	**90.91%**
	The questionnaire covers functional aspects adequately	**100%**
	The questionnaire is adequate as a “Pre-treatment Questionnaire for Orthodontic Patients”	**100%**
Overall Agreement		**97.52%**
Patients (N = 20)	The content of this questionnaire is appropriate for patients before orthodontic treatment	**100%**
	The phrases within the questionnaire are clear and are easily understood	**100%**
	The questionnaire is easy to follow and is in logical order	**100%**
	The questionnaire is consistent in terms of style and layout	**100%**
Overall Agreement		**100%**

Table 18: Recommendations provided by professionals and patients to improve the Pre-treatment Questionnaire (first round)

Recommendations	Aspects not Addressed	Corrections
May be to add "To make me brush or clean my teeth properly or easily"	An expectation of easier tooth brushing following braces treatment	Add *"To make it easier to brush my teeth"*
Functional and aesthetic questions are quite similar and repetitive		Merge repetitive questions/items
There is a significant repetition in the questions		
The question about school work may be adapted as many of our patients are adults?		Items were removed (not valid)
School work could be changed to school or work		
Large amount of adult patients, so schoolwork/work life representation is important		
Questions seem directed to children/teenagers. Perhaps more adult questions **(Patient)**		
Jaw joint explanation required?		Items were removed (not valid)
Reasons regarding families and friends don't seem relevant **(Patient)**		Items were removed (not valid)
	A question related to headache/jaw clicking may be useful **(Patient)**	Add *"To stop/prevent pain in my jaws/joints"*
	A question about preventing or stopping pain would be useful **(Patient)**	
	Not sure that psychological aspects can be covered adequately here	

3.1.7.1.2 Modifications

According to the results of the first round of content and face validation, the following steps were carried out:

1. The non-valid items were removed.
2. Two items were added; “To make it easier to brush my teeth” (professional recommendation) and "To stop/prevent pain in my jaws/joints” (patient recommendation).
3. Similar and repetitive items were merged together (six items were merged to become three items) (Table 19)

Following these modifications, the total number of items, therefore, became 11 and the questionnaire was re-checked in the second round of validation.

Table 19: Merged items in the Pre-treatment Questionnaire

Item	New Merged Item
To make my face look better	To make my face look better
To make me look better	
To feel more confident	To make me more confident and feel better about myself
To make me feel better about myself	
To help me chew food better	To help me chew food more easily
To make it easier to bite into food	

3.1.7.1.3 Second Round of Validation

3.1.7.1.3.1 Content Validity

Only one of the additional items (related to pain) was not content valid (I-CVI = 0.57). However, the overall questionnaire had almost perfect content validity (S-CVI/Ave = 0.95) and after removing the non-valid item, the S-CVI/Ave increased to 0.99. Only one item had I-CVI = 0.86, while nine items had I-CVI = 1 (Table 20). The feedback from the experts in this round recommended re-including the non-valid item “To make it

easier to get on with people" and to merge it with "To make me feel better about going out" in order to match the same item in the Post-treatment Questionnaire.

3.1.7.1.3.2 Face Validity with Respondents

All the ten patients indicated that the questionnaire was clear, understandable, easy to follow and had a consistent format and layout. No further recommendations were provided.

The new version of the Pre-treatment Questionnaire comprising ten items was therefore found to be almost perfect in terms of content and face validity (Appendix 15).

Table 20: Content validity results for each item in the modified Pre-treatment Questionnaire (second round)

Item	I-CVI
To make my teeth look better	**1.00**
To make my smile better	**1.00**
To make my face look better	**1.00**
To make me more confident and feel better about myself	**1.00**
To make me feel better about going out	**1.00**
To help my top and bottom teeth fit together	**1.00**
To help my front teeth fit together	**1.00**
To help my back teeth fit together	**0.86**
To help me chew food more easily	**1.00**
To make it easier to brush my teeth	**1.00**
To stop/prevent pain in my jaws/joints	**0.57**
S-CVI/Ave	**0.95**

3.1.7.2 Smiles-Better Questionnaire

3.1.7.2.1 First Round of Validation

3.1.7.2.1.1 Content Validity

Only 21 items were content valid and relevant to the construct under investigation (I-CVI ≥ 0.80), while 38 items were non-valid (I-CVI < 0.80). The overall questionnaire was also non-valid (S-CVI/Ave = 0.60). Table 21 summarises the results of content validity for the Smiles-Better Questionnaire.

3.1.7.2.1.2 Face Validity with Professionals

The results showed that the questionnaire had an excellent face validity as a "Questionnaire for Orthodontic Patients during Treatment" (overall agreement = 97.73%). All the professionals reported that the questionnaire was appropriate and relevant for orthodontic patient experience throughout treatment, addressed changes and discomfort that happen during treatment, and covered the major aesthetic, social, oral health, and functional aspects. Ten of the 11 professionals thought that the questionnaire was easily understood, had a consistent format and style, and covered the psychological aspects adequately (Table 22). Recommendations were also provided by the professionals and one mentioned a few aspects that were not addressed. Table 23 illustrates these together with the recommendations of patients.

3.1.7.2.1.3 Face Validity with Respondents

All the 20 patients reported that the questionnaire had an excellent face validity (overall agreement = 98.75%) as it was clear and easily understood, easy to follow and in a logical order, and was consistent in terms of style and layout. The vast majority of the patients (19 patients) believed that the content was appropriate for patients with braces (Table 22) and only two added recommendations and notes (Table 23).

Table 21: Content validity results for each item in the Smiles-Better Questionnaire (first round)

Category	Item	I-CVI
Changes Because of Wearing Your Brace	Speech	**0.70**
	Eating	**0.80**
	Drinking	**0.70**
	Sleeping	**0.50**
	Appearance	**1.00**
	I am teased	**1.00**
How have the Followings Affected You?	Sore teeth	**1.00**
	Soreness in your mouth	**1.00**
	Soreness from rubbing	**0.90**
	Feeling embarrassed	**0.80**
	Dribbling	**0.60**
	Keeping the brace clean is a nuisance	**1.00**
Schoolwork	How have any changes in your speech affected your schoolwork?	**0.50**
	How have any changes in your eating affected your schoolwork?	**0.20**
	How have any changes in how you drink affected your schoolwork?	**0.00**
	How have any changes in your sleep patterns affected your schoolwork?	**0.20**
	How have any changes in your appearance affected your schoolwork?	**0.60**
	If you have experienced teasing how has it affected your schoolwork?	**0.80**
	Sore teeth	**0.80**
	Soreness in your mouth	**0.80**
	Soreness from rubbing	**0.70**
	Feeling embarrassed	**0.70**
	Dribbling	**0.20**
	Keeping the brace clean	**0.50**
Getting on with Friends	How have any changes in your speech affected your friendship?	**0.50**
	How have any changes in your eating affected your friendship?	**0.30**
	How have any changes in how you drink affected your friendship?	**0.10**
	How have any changes in your sleep patterns affected your friendship?	**0.10**
	How have any changes in your appearance affected your friendship?	**0.90**
	If you have experienced teasing how has it affected your friendship?	**0.90**
	Sore teeth	**0.10**
	Soreness in your mouth	**0.10**
	Soreness from rubbing	**0.10**
	Feeling embarrassed	**0.70**
	Dribbling	**0.40**
	Keeping the brace clean	**0.40**
Family Relationships	How have any changes in your speech affected your relationship with your family?	**0.50**
	How have any changes in your eating affected your relationship with your family?	**0.50**
	How have any changes in how you drink affected your relationship with your family?	**0.10**
	How have any changes in your sleep patterns affected your relationship with your family?	**0.50**
	How have any changes in your appearance affected your relationship with your family?	**0.80**

Category	Item	I-CVI
	If you have experienced teasing how has it affected your relationship with your family?	**0.90**
	Sore teeth	**0.50**
	Soreness in your mouth	**0.50**
	Soreness from rubbing	**0.50**
	Feeling embarrassed	**0.70**
	Dribbling	**0.40**
	Keeping the brace clean	**0.60**
Hobbies/Interests	Music	**0.80**
	Sport	**0.60**
	Drama	**0.60**
	Singing	**0.60**
	Going to clubs e.g. scouts or guides	**0.40**
Tooth Movement	Now that you are wearing a brace, do you feel that your teeth are moving?	**0.90**
	Is it important to you whether or not your teeth are moving?	**0.70**
Your Experience of Wearing a Brace	Is wearing a brace what you expected?	**1.00**
	Have you had any extra visits to the hospital because your brace has broken?	**0.80**
	If you have had to make extra visits because your brace has broken, has this bothered you?	**0.90**
Your Advice to Other Patients	Based upon YOUR experience of wearing a brace, what would YOU say to someone who was about to have a brace fitted?	**1.00**
S-CVI/Ave		**0.60**

Table 22: Face validity results with professionals and patients for the Smiles-Better Questionnaire (first round)

Panel	Domains	% of Validity
Professionals (N = 11)	The content of the questionnaire is appropriate for patient experience throughout treatment	**100%**
	The questionnaire addresses changes and discomforts that happened during treatment	**100%**
	The content of the questionnaire is appropriate and relevant for orthodontic patients	**100%**
	The phrases of the questionnaire are easily understood	**90.91%**
	The questionnaire has consistent format and style	**90.91%**
	The questionnaire covers the most important aspects of patient perception throughout treatment	**100%**
	The questionnaire covers aesthetic aspects adequately	**100%**
	The questionnaire covers social aspects adequately	**100%**
	The questionnaire covers psychological aspects adequately	**90.91%**
	The questionnaire covers oral health aspects adequately	**100%**
	The questionnaire covers functional aspects adequately	**100%**
	The questionnaire is adequate as a "Questionnaire for Orthodontic Patients during Treatment"	**100%**
Overall Agreement		**97.73%**
Patients (N = 20)	The content of this questionnaire is appropriate for patients with braces	**95%**
	The phrases within the questionnaire are clear and are easily understood	**100%**
	The questionnaire is easy to follow and is in logical order	**100%**
	The questionnaire is consistent in terms of style and layout	**100%**
Overall Agreement		**98.75%**

Table 23: Recommendations provided by professionals and patients to improve the Smiles-Better Questionnaire (first round)

Recommendations	Aspects not Addressed	Corrections
Could the title of questionnaire "Smiles-Better" influence a patient view in a positive way implying everyone must be feeling better with braces?		The title of the questionnaire changed to *"Orthodontic Experience Questionnaire"*
Question 1 regarding teasing may be a little confusing for those patients who have not been teased previously or are being teased at present. There is no box to tick for this and patients may be unsure how to answer this question		The first teasing question had been modified to *"If you were called names or bullied about your teeth before you started treatment, has this changed?"* Teasing word had been changed to *"Called names or bullied"*
Some patients ask what "teasing" means. May require rewording		
"Teasing" question is confusing, is teasing due to malocclusion before braces or because of braces?		
The questionnaire should be adapted for adult patients by asking questions about work rather than schoolwork		Change schoolwork to *"school or work"*
Some of the questions are directed to school age patients. May need to modify this to school/work		
Schoolwork could be changed to school or work		
"Schoolwork" section is not appropriate for adults		
The questions are targeted to children/young adults and are not valid for adults **(Patient)**		
Questions are directed at kids. May be more adult questions **(Patient)**		
Significant repetition in the questions		Merge repetitive questions/items
It is perhaps a little long especially for the younger patients		Should be shortened by merging repetitive questions and removing not valid items
Long questionnaire; could be shorter		
You offer "improved, same, slightly worse, much worse" as possible responses. Try to balance the rating so there are as many positive as negative responses available		The option of *"much worse"* in the rating was removed and *"slightly worse"* was changed to *"worse"*
It is better to replace "same" answer option by "no change"		Add *"no change"* instead of *"same"* as an option to the answers
Question "is wearing a brace what you expected" is better to be near the front **(Patient)**		Change the position of this question and its section to the front
	Psychology is difficult to be covered here	

3.1.7.2.2 Modifications

According to the results of the first round of content and face validation, the following steps were carried out:

1. The non-valid items were removed.
2. The title of the questionnaire was changed to “Orthodontic Experience Questionnaire”.
3. “Teasing” was modified to “Called names or bullied”.
4. The first question about teasing was modified to “If you were called names or bullied about your teeth before you started brace treatment, has this changed?”
5. “Schoolwork” was changed to “school or work” to include all age groups.
6. Similar and repetitive items were merged together in order to reduce the repetition as well as the length of the questionnaire. Since the valid items of friendship and family relationship categories were the same, the professionals recommended merging them together with one heading “Getting on with Friends and Family” (four items merged to be two).
7. Answer options were balanced by removing the “Much worse” option.
8. The “Same” answer option was replaced by “No change” to fit better with the phrasing of the questions.
9. Questions about the “experience of wearing a brace” and “tooth movement” were moved to the first section in the questionnaire under the first heading.
10. Some headings and items were modified to make them clearer.

Therefore, the total number of items became 19. As with the Pre-treatment Questionnaire, the Smiles-Better Questionnaire (Orthodontic Experience Questionnaire) then passed through a second round of validation following these corrections.

3.1.7.2.3 Second Round of Validation

3.1.7.2.3.1 Content Validity

All the items were content valid and the questionnaire as a whole was also content valid (S-CVI/Ave = 0.97). Fifteen items received total agreement (I-CVI = 1.00) and four items had I-CVI = 0.86 (Table 24). The panel recommended moving the item “Keeping the brace clean is a nuisance” to the first section of the experience of wearing a brace and to change the word “visits” to “appointments”.

3.1.7.2.3.2 Face Validity with Respondents

The modified questionnaire was considered as having appropriate face validity because all the ten patients confirmed that it was clear, understandable, easy to follow and had a consistent format and layout. There were no further recommendations.

The new version of the Orthodontic Experience Questionnaire consisted of 19 items and was found to have adequate content and face validity (Appendix 16).

Table 24: Content validity results for each item in the modified Smiles-Better Questionnaire (Orthodontic Experience Questionnaire) (second round)

Category	Item	I-CVI
Your Experience of Wearing a Brace	Is wearing a brace what you expected?	**1.00**
	Have you had any extra visits to the hospital because your brace has broken?	**1.00**
	If you have had to make extra visits because your brace has broken, has this bothered you?	**1.00**
	Now that you are wearing a brace do you feel that your teeth are moving?	**0.86**
	Keeping the brace clean is a nuisance	**1.00**
Changes due to Wearing Your Brace	Eating	**1.00**
	Appearance	**1.00**
	If you were called names or bullied about your teeth before you started treatment, has this changed?	**1.00**
How have the Followings Affected You?	Sore teeth	**1.00**
	Soreness in your mouth	**1.00**
	Soreness from rubbing	**1.00**
	Feeling embarrassed	**1.00**
School or Work	Sore teeth	**0.86**
	Soreness in your mouth	**0.86**
	Called names or bullied due to your brace	**1.00**
Getting on with Friends and Family	Changes in your appearance	**0.86**
	Called names or Bullied	**1.00**
Hobbies/Interests	e.g. Music	**1.00**
Your Advice to Other Patients	Based upon YOUR experience of wearing a brace, what would YOU say to someone who was about to have a brace fitted?	**1.00**
S-CVI/Ave		**0.97**

3.1.7.3 After (Post) Treatment Questionnaire

3.1.7.3.1 First Round of Validation

3.1.7.3.1.1 Content Validity

Only 12 items were content valid and relevant to the construct under investigation (I-CVI ≥ 0.80), while ten items were non-valid (I-CVI < 0.80). The CVI for the overall questionnaire (S-CVI/Ave) was 0.64, which is below the threshold for questionnaire validity (0.90). The non-valid items were therefore deleted. Table 25 summarises the results of content validity for the Post-treatment Questionnaire.

3.1.7.3.1.2 Face Validity with Professionals

The results showed that all the 11 professionals considered the questionnaire as having appropriate face validity to be used as a "Post-treatment Questionnaire for Orthodontic Patients" (overall agreement = 98.35%) because it was suitable and relevant for post-treatment orthodontic patients, easily understood, had a consistent format and style, and covered the major aesthetic, social, and functional aspects. The questionnaire was considered to cover the psychological and oral health aspects adequately by 10 of the 11 professionals (Table 26). Similar to other questionnaires, the professionals provided their suggestions to improve the questionnaire and two of them highlighted a few other aspects that were not addressed (Table 27).

3.1.7.3.1.3 Face Validity with Respondents

Twenty patients reviewed the questionnaire and the results of the ratings showed that the questionnaire was valid (overall agreement = 100%) as it had an appropriate content for patients following orthodontic treatment, was clear and easily understood, easy to follow and in a logical order, and was consistent in terms of style and layout (Table 26). One patient provided recommendations to improve the questionnaire further (Table 27).

Table 25: Content validity results for each item in the Post-treatment Questionnaire (first round)

Validity	N	Item	I-CVI
Valid Items	1	It has made my teeth look nicer	**1.00**
	2	It has made my face look better	**0.90**
	3	It has made me look better	**1.00**
	4	It has made me more confident	**1.00**
	5	It has made me feel better about myself	**1.00**
	6	It has made me feel better about going out	**1.00**
	7	It has made it easier to get on with people	**0.80**
	8	It has helped my top and bottom teeth fit together	**1.00**
	9	It has helped my front teeth fit together	**1.00**
	10	It has helped my back teeth fit together	**0.80**
	11	It has made it easier to chew my food	**0.80**
	12	It has made it easier to bite into food	**0.90**
Non Valid Items	1	It has made my family happier	**0.30**
	2	It has helped me with my schoolwork	**0.20**
	3	It has helped my breathing	**0.10**
	4	It has helped me speak more clearly	**0.40**
	5	It has made my gums healthier	**0.60**
	6	It has made me healthier	**0.10**
	7	It will stop me losing teeth in the future	**0.10**
	8	It is easier to make friends	**0.70**
	9	It has helped to keep my jaw joints healthy	**0.10**
	10	It keeps my jaw joint from clicking	**0.20**
S-CVI/Ave			**0.64**

Table 26: Face validity results with professionals and patients for the Post-treatment Questionnaire (first round)

Panel	Domains	% of Validity
Professionals (N = 11)	The content of the questionnaire is appropriate as a post-treatment patient satisfaction index	**100%**
	The content of the questionnaire is appropriate and relevant for orthodontic patients	**100%**
	The phrases of the questionnaire are easily understood	**100%**
	The questionnaire has consistent format and style	**100%**
	The questionnaire covers the most important aspects of post-treatment patient satisfaction	**100%**
	The questionnaire covers aesthetic aspects adequately	**100%**
	The questionnaire covers social aspects adequately	**100%**
	The questionnaire covers psychological aspects adequately	**90.91%**
	The questionnaire covers oral health aspects adequately	**90.91%**
	The questionnaire covers functional aspects adequately	**100%**
	The questionnaire is adequate as a "Post-treatment Questionnaire for Orthodontic Patients"	**100%**
Overall Agreement		**98.35%**
Patients (N = 20)	The content of this questionnaire is appropriate for patients after braces	**100%**
	The phrases within the questionnaire are clear and are easily understood	**100%**
	The questionnaire is easy to follow and is in logical order	**100%**
	The questionnaire is consistent in terms of style and layout	**100%**
Overall Agreement		**100%**

Table 27: Recommendations provided by professionals and patients to improve the Post-treatment Questionnaire (first round)

Recommendations	Aspects not Addressed	Corrections
No question about smile		Add *"It has made my smile look better"*
May be to add "It has made it easier to brush or clean my teeth"	An expectation of easier tooth brushing following braces treatment	Add *"It is easier to brush my teeth"*
No mention of brushing		
Some questions are similar to each other		Merge repetitive questions/items
Significant repetition in the questions		
Some of the questions are quite similar **(Patient)**		
Large amount of adult patients, so schoolwork/work life representation is important		Items were removed (not valid)
Schoolwork could be changed to school or work		
The questionnaire seems to be designed for children and not adults **(Patient)**		
Questions seem directed to children/teenagers. Perhaps more adult questions **(Patient)**		
	Need a question about remaining pain e.g. "My teeth no longer hurt me/cut my mouth" **(Patient)**	Add *"My jaw/joint pain is better"*
	I believe psychology is more complex	

3.1.7.3.2 Modifications

According to the results of the first round of content and face validation, the following steps were carried out:

1. The non-valid items were removed.
2. Three items were added; “It has made my smile look better”, “It is easier to brush my teeth” (professional recommendation), and “My jaw/joint pain is better” (patient recommendation).
3. Similar and repetitive items were merged together (eight items were merged to become four items) (Table 28).

Following these modifications, the total number of items, therefore, became 11 and the questionnaire was ready for the second round of validation.

Table 28: Merged items in the Post-treatment Questionnaire

Item	New Merged Item
It has made my face look better	It has made my face look better
It has made me look better	
It has made me more confident	It has made me more confident and I feel better about myself and going out
It has made me feel better about myself	
It has made me feel better about going out	It has made me feel better about going out and easier to get on with people
It has made it easier to get on with people	
It has made it easier to chew my food	It has made it easier to chew my food
It has made it easier to bite into food	

3.1.7.3.3 Second Round of Validation

3.1.7.3.3.1 Content Validity

The results revealed that only one of the additional items (related to pain) was not valid (I-CVI = 0.57). However, the overall questionnaire had almost perfect content validity (S-CVI/Ave = 0.94) prior to removing the non-valid item which increased to 0.97 when removed. Eight items received a total agreement (I-CVI = 1.00), while two items had I-CVI = 0.86 (Table 29).

3.1.7.3.3.2 Face Validity with Respondents

The questionnaire retained face validity as all of the patients reported that the questionnaire was clear, understandable, easy to follow and had a consistent format and layout. No additional recommendations were required.

The new version of the Post-treatment Questionnaire consisted of ten items and was found to have high levels of both content and face validity (Appendix 17).

Table 29: Content validity results for each item in the modified Post-treatment Questionnaire (second round)

Item	I-CVI
It has made my teeth look better	**1.00**
It has made my smile better	**1.00**
It has made my face look better	**1.00**
It has made me more confident and I feel better about myself	**1.00**
It has made me feel better about going out and easier to get on with people	**0.86**
It has helped my top and bottom teeth fit together	**1.00**
It has helped my front teeth fit together	**1.00**
It has helped my back teeth fit together	**0.86**
It has made it easier to chew my food	**1.00**
It is easier to brush my teeth	**1.00**
My jaw/joint pain is better	**0.57**
S-CVI/Ave	**0.94**

3.1.7.4 Reliability

3.1.7.4.1 Internal Consistency

The Cronbach alpha coefficient was used to test internal consistency for the retained items in the Pre- and Post-treatment Questionnaires which were completed by the RCT participants. Therefore, the new items were not included in the test and the results demonstrated that both the Pre- and Post-treatment Questionnaires have good internal consistency reliability (α = 0.86 and 0.88, respectively) (Tables 30 and 31). The same test was used to assess internal consistency for the whole Orthodontic Experience Questionnaire. Three items were not included in the final model, two because of their nominal nature (unlike the rest that were ordinal), namely; “Is wearing a brace what you expected?” and “Have you had any extra appointments to the hospital because your brace has broken?” and the third excluded item was the effect on hobbies/interest because it was a separate item. The final model, therefore, consisted of 18 valid items and the result was acceptable (α = 0.78) (Table 32). An attempt was then made to cluster items using principal components factor analysis and consequently, two main groups or domains were developed (multi-dimensional questionnaire). These explained 41.5% of the variance. The first group included ten items measuring function, self-concept and interpersonal relations, which involved 26.5% of the variance (eigen value = 4.78) and had appropriate internal consistency (α = 0.82). The second group included six items measuring pain and experience with fixed appliances. It comprised 14.9% of the variance (eigen value = 2.70) and had an acceptable Cronbach alpha value (α = 0.71) (Table 33). Two items, related to tooth movement and cleaning of a brace were not included in the above groups due to the low factor loading.

Table 30: Cronbach alpha (internal consistency) for the whole Pre-treatment Questionnaire

Item	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
To make my teeth look nicer	31.03	52.68	0.47	0.85
To make my smile nicer	31.29	49.68	0.66	0.84
To make my face look better	32.34	47.88	0.54	0.85
To make me look better	31.86	45.07	0.72	0.84
To feel more confident	31.69	45.93	0.70	0.84
To make me feel better about myself	31.80	45.11	0.76	0.83
To make me feel better about going out	32.46	43.43	0.79	0.83
To make it easier to get on with people	33.66	55.70	0.15	0.87
To help my top and bottom teeth fit together	31.46	50.84	0.45	0.85
To help my front teeth fit together	31.46	47.73	0.62	0.84
To help my back teeth fit together	32.03	48.21	0.48	0.85
To help me chew food better	33.11	55.05	0.13	0.87
To make it easier to bite into food	33.09	53.49	0.23	0.87
Cronbach Alpha				**0.86**
Number of Valid Cases				**35**

Table 31: Cronbach alpha (internal consistency) for the whole Post-treatment Questionnaire

Item	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
It has made my teeth look nicer	31.86	49.95	0.55	0.87
It has made my face look better	32.69	43.75	0.65	0.86
It has made me look better	32.43	45.66	0.69	0.86
It has made me more confident	32.34	45.35	0.77	0.86
It has made me feel better about myself	32.34	44.58	0.74	0.86
It has made me feel better about going out	32.83	44.91	0.55	0.87
It has made it easier to get on with people	34.00	49.82	0.29	0.89
It has helped my top and bottom teeth fit together	32.40	45.42	0.62	0.87
It has helped my front teeth fit together	32.23	48.65	0.46	0.87
It has helped my back teeth fit together	32.51	44.67	0.65	0.86
It has made it easier to chew my food	33.20	48.75	0.43	0.88
It has made it easier to bite into food	33.09	44.43	0.59	0.87
Cronbach Alpha				**0.88**
Number of Valid Cases				**35**

Table 32: Cronbach alpha (internal consistency) for the whole Orthodontic Experience Questionnaire

Item	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
If you have had to make extra appointments because your brace has broken, has this bothered you?	29.87	19.71	0.19	0.78
Now that you are wearing a brace, do you feel that your teeth are moving?	29.43	19.63	0.05	0.79
Overall experience	29.30	19.11	0.13	0.79
Appearance	29.27	16.27	0.53	0.75
If you were called names or bullied about your teeth before you started treatment, has this changed?	29.33	17.47	0.48	0.76
Feeling embarrassed	29.73	17.86	0.52	0.76
Being called names or bullied due to your brace (School or Work)	29.03	18.86	0.41	0.76
Appearance (Friendship)	29.20	17.34	0.65	0.75
Being called names or bullied due to your brace (Friendship)	29.10	19.33	0.28	0.77
Appearance (Family)	29.07	18.48	0.48	0.76
Being called names or bullied due to your brace (Family)	28.97	19.27	0.42	0.77
Eating	28.50	17.50	0.52	0.75
Having to keep the brace clean is a nuisance	29.43	19.98	0.00	0.79
Sore teeth	28.97	18.31	0.33	0.77
Soreness in your mouth	29.17	17.87	0.46	0.76
Soreness from rubbing	29.03	17.21	0.42	0.76
Sore teeth (School or Work)	29.47	18.19	0.37	0.77
Soreness in your mouth (School or Work)	29.57	17.98	0.42	0.76
Cronbach Alpha				**0.78**
Number of Valid Cases				**30**

Table 33: Cronbach alpha for the two groups emerged from the Orthodontic Experience Questionnaire using principal components factor analysis (Number of valid cases = 33)

Domain	Cronbach Alpha	Factor Loading
Group 1: Function, self-concept, and interpersonal relation	**0.82**	
Appearance		0.62
If you were called names or bullied about your teeth before you started treatment, has this changed?		0.75
Feeling embarrassed		0.50
Being called names or bullied due to your brace (School or Work)		0.74
Appearance (Friendship)		0.89
Being called names or bullied due to your brace (Friendship)		0.62
Appearance (Family)		0.64
Being called names or bullied due to your brace (Family)		0.64
Eating		0.62
Soreness from rubbing		0.49
Group 2: Pain and experience of wearing a brace	**0.71**	
If you have had to make extra appointments because your brace has broken, has this bothered you?		0.33
Overall experience		0.23
Sore teeth		0.73
Soreness in your mouth		0.80
Sore teeth (School or Work)		0.70
Soreness in your mouth (School or Work)		0.80

3.1.8 Discussion

This study was designed to assess the validity of three questionnaires for the evaluation of patient perception with fixed appliance orthodontic treatment. As the modified questionnaires demonstrated high levels of validity and good reliability, the null hypothesis was rejected. The questionnaires were initially developed for the evaluation of patient perception and experience with functional appliances, so it is reasonable that some items in the original versions were not relevant to fixed appliance treatment. Although the development process of original questionnaires was opaque and perhaps did not follow a well-established methodology, two rounds of validation were undertaken to improve the contents. Content validity is important for every scale/questionnaire because it ensures that the contents are relevant and representative of the targeted construct and respondents. Otherwise, the data might not fully represent some important aspects of the construct or alternatively could measure variables from outside the construct domains and consequently, the clinical implications derived from that scale would be misleading (Haynes et al., 1995; Waltz et al., 2010). It has also been pointed out that content validity is an essential and primary test for any new or revised scale. It cannot be preceded or substituted by other tests but can be followed by reliability tests or other types of validity such as construct validity or criterion-related validity (Rubio et al., 2003; Zumbo and Chan, 2014; Zamanzadeh et al., 2015).

3.1.8.1 Content Validity

The quality of content validity of a questionnaire is based on the collective opinion and rating by experts. This depends on their level of experience in the content area and can be considerably compromised by one or more poor content experts (Waltz et al., 2010; Sangoseni, 2013). The expert judges in this validation were selected from university dental hospitals and district general hospitals with adequate clinical experience in the content field under investigation. The criteria for the selection of the content experts as

well as the clear information provided to them about the content construct and domains and the design of the cover invitation letter were all in accordance with the instructions provided by Grant and Davis (1997) and Rubio et al. (2003). It has also been mentioned that increasing the number of content reviewers to greater than five can account for artificially inflated CVIs or inter-rater agreement occurring by chance and aids in identifying and excluding outliers, as well as increasing the robustness of the ratings (Lynn, 1986; Haynes et al., 1995). The number of the expert reviewers and the use of the 4-point Likert scale were consistent with the recommendations of Lynn (1986), Polit and Beck (2006), Polit et al. (2007) and Parsian and Trish Dunning (2009).

Although one round can be acceptable for validation, all the questionnaires in the current study were assessed using two validation rounds in order to allow the questionnaires to be modified and to improve their robustness. Lynn (1986), Haynes et al. (1995), Rubio et al. (2003) and Polit et al. (2007) recommended using two rounds of validation or multiple revisions for further refinement unless only minor and insignificant modifications are required. Moreover, Polit et al. (2007) suggested inviting a larger expert panel in the first round (about 8-12 experts) and a smaller panel in the second round (about 3-5 experts). For this study, ten experts participated in the first round and seven in the second round. The high number of non-valid items in the Smiles-Better Questionnaire could be explained because it was relatively long with a lot of repetitive items. For that reason, both experts and respondents recommended the number of items to be reduced. The relevant items in the current study had received percentages of agreement in accordance with both Lynn (1986) and Polit et al. (2007) (it would fall within an excellent range of kappa analysis of 0.75 or higher).

Questions about tooth brushing were added both to the Pre- and Post-treatment Questionnaires as they were considered by experts as one of the important missing

aspects because food accumulation is usually associated with fixed appliances more than functional appliances and since the questionnaires were originally developed for functional appliances so they did not include such questions. Similarly, the “smile” question was added to the Post-treatment Questionnaire due to the importance of smiling for overall facial aesthetics and the close relation of this to orthodontic treatment, as well as to match the Pre-treatment Questionnaire which includes a similar item. On the other hand, two patients in the first round felt that adding questions about dental and jaw pain would be beneficial for both the Pre- and Post-treatment Questionnaires. However, these items were removed in the second round. This was because the experts reported that pain is not one of the reasons for seeking orthodontic treatment. This conflict between patients and experts was interesting. The added item (pain in jaws) was recommended by a minority of respondents (2 of 20 patients), whilst the majority of the experts believed that it was not content relevant. In this situation, a balance should be made between the weakest form of validity (face validity by patients) and the more robust form (content validity by experts). Consequently, the finding of content validity is more robust and resulted in the retention of only the most relevant items, such as the pain questions in the Orthodontic Experience Questionnaire because pain is experienced during fixed appliance orthodontic treatment.

The redundancy of items that mapped to similar aspects of the construct, such as “To make my face look better” and “To make me look better” as indicated by some assessors, allowed these to be merged so that the questionnaires were shorter and easier to answer.

Some modifications were found to be useful for the Smiles-Better Questionnaire. The title was changed to the “Orthodontic Experience Questionnaire” to reduce the influence on patients’ answers about smile and appearance. The word “Teasing” was vague and

confusing for many patients, therefore it was modified to “Called names or bullied”. Although using question with double items may disagree with Marshman et al. (2010), this was added according to the feedback with both professionals and patients. Similarly, the item “I am teased” was modified to be “If you were called names or bullied about your teeth before you started treatment, has this changed?” in an attempt to decrease ambiguity for patients who have not been teased previously as well as to eliminate any confusion about whether teasing was due to the pre-treatment malocclusion or due to appliances. One of the most important modifications related to the “Schoolwork” items because this questionnaire was originally intended to be used by a school age group who can be treated with functional appliances. As a result, it was modified to “School or Work” to be more broadly applicable to all age groups.

In order to balance the rating options (Improved; No change; Worse/Slightly worse; and Much worse), the “Much worse” category was removed with “Slightly worse” changed to “Worse”. It was also suggested that the items relating to the experience of wearing an appliance and tooth movement would be more logical at the beginning of the questionnaire before asking more sensitive questions such as those related to appearance, name-calling, bullying and embarrassment.

In the second round of validation, the three questionnaires had excellent overall content validity of 0.95, 0.97, and 0.94 for the Pre-treatment, Orthodontic Experience, and Post-treatment Questionnaires, respectively. Removing the two items that were related to jaw pain from the Pre- and Post-treatment Questionnaires as described above has enhanced the S-CVI/Ave for the Pre-treatment Questionnaire to 0.99 and that for the Post-treatment Questionnaire to 0.97. Two experts recommended re-including the non-valid item “To make it easier to get on with people” which was initially removed in the first round from the Pre-treatment Questionnaire and to merge it with “To make me feel

better about going out" so that the new form would be "To make me feel better about going out and easier to get on with people". The reason for this was justified because this new form could be more meaningful as well as to match the similar item in the Post-treatment Questionnaire: "It has made me feel better about going out and easier to get on with people". In the Orthodontic Experience Questionnaire, the feedback recommended changing the item "Keeping the brace clean is a nuisance" to "Having to keep the brace clean is a nuisance" and placed it in the first section of experience of wearing a brace as it is more related to that section. A few other linguistic modifications were also made, such as changing "visits" to "appointments" (Appendix 16).

It is worth mentioning that Polit and Beck (2006) reported two methods for calculating the scale level CVI. The liberal method or S-CVI/Ave (average proportion) which is obtained by averaging the I-CVI was considered by Polit and Beck (2006) as the best way of measuring the S-CVI because it focuses on average item quality and was therefore used in this study. The minimum acceptable value for the S-CVI/Ave is 0.90 (Waltz et al., 2005). The second is the conservative method or S-CVI/UA (universal agreement) which is the proportion of items that are rated as relevant by *all* the experts. This method (S-CVI/UA) is more stringent and difficult to achieve especially when the number of experts increases. The minimum acceptable value for the S-CVI/UA is 0.80 (Davis, 1992). Although in this study the S-CVI/Ave was calculated, if the S-CVI/UA is applied for the final version of the questionnaires, the results would be 0.90 for the Pre-treatment Questionnaire, 0.79 for the Orthodontic Experience Questionnaire, and 0.80 for the Post-treatment Questionnaire. All the above values could be accepted within the universal agreement method.

3.1.8.2 Face Validity

For face validity, there was no specific method to be followed. It was therefore decided to evaluate this by achieving an adequate percentage of agreement for each parameter and for the overall questionnaire in the feedback form for professionals and patients. The face validity form was designed in a systematic approach in order to improve the quality of face validity assessment per Trochim et al. (2015). It was surprising to find that the three questionnaires had adequate face validity even in the first round of validation when they were not content valid. This supports the claim that face validity is the weakest form of validation and using it alone unaided by other types of validation might lead to spurious results. Waltz et al. (2010) mentioned that face validity does not represent validity in its true sense where there is evidence that the questionnaire is measuring what it was intended to measure, but it only indicates that the scale or questionnaire is apparently measuring what it was claimed to measure (upon review by laypersons). This would, in turn, encourage respondents and could increase the response rate. However, in this study both content and face validation complemented each other because the qualitative feedback was incorporated with the face validation, which was important for adding and modifying some items and this can also be considered as a part of content or pre-content validation. Moreover, both professionals and patients were included in this face validation. This was in line with Lynn (1986) who emphasised the importance of asking experts to identify if any important aspects have been omitted and whether they have recommendations or modifications to improve the items. Additionally, face to face interviews with the targeted group of respondents and receiving their qualitative feedback were indicated by Grant and Davis (1997) and Zamanzadeh et al. (2015) as an important supplement to the content validity of any scale.

3.1.8.3 Reliability

Reliability of the three questionnaires was measured using the Cronbach alpha test for internal consistency. Test-retest reliability was not evaluated due to the change in respondents' situations. This was in accordance with DeVon et al. (2007) who stated that test-retest reliability is not suitable for scales or conditions that are changeable over time such as mood, attitude or knowledge especially when there is an intervention. The whole Orthodontic Experience Questionnaire and two domains emerging from it measuring appearance and pain (mainly) had adequate internal consistency (α = 0.78, 0.82, and 0.71, respectively) (Claassens et al., 2015; Hudon et al., 2015; Momayyezi et al., 2015; Hanson et al., 2016) and these explained 41.5% of the variance. These two domains included only 16 items, while the non-included items were considered either as individual items testing different aspects of the same construct so they may not be highly correlated with each other or with the total score, or they had low factors loading (< 0.2) and consequently, these were removed by the analysis. The Pre- and Post-treatment Questionnaires also demonstrated good internal consistency (α = 0.86 and 0.88, respectively).

After completing the new versions, the layout of the final questionnaires was adjusted according to the suggestions of Brace, (2008) and Bowling (2009).

3.1.8.4 Comparison with Other Questionnaires

Modifying a questionnaire is not an uncommon procedure. Bos et al. (2003) used a questionnaire designed for patients undergoing orthognathic surgery and modified it in order to be used for orthodontic patients. Several modifications to OHRQoL questionnaires for orthodontic patients have been described. However, authors have modified/used generic OHRQoL questionnaires to measure the impact of malocclusion on quality of life (O'Brien et al., 2006) orthodontic-specific aspects on quality of life

(e.g. psychosocial impact of dental aesthetics) (Klages et al., 2006) or the impact of pain during orthodontic treatment on quality of life (Iwasaki et al., 2013). Moreover, previously published valid and reliable questionnaires have limitations, for example, they were designed for specific age groups and since orthodontic treatment takes a long time, a questionnaire developed for participants at the start of treatment might not be appropriate at the end of treatment, this includes newly developed questionnaires (Bennett et al., 1997; Bennett et al., 2001; Klages et al., 2006; Mandall et al., 2006a; Sayers and Newton, 2006; Feldmann et al., 2007; Pabari et al., 2011) or using a previously developed questionnaires (O'Brien et al., 2006; Iwasaki et al., 2013; Benson et al., 2016). Other limitations are related to the aims of existing questionnaires, which developed to measure either motivation, expectations, experiences, or satisfaction (Bennett et al., 1997; Bennett et al., 2001; Klages et al., 2006; Mandall et al., 2006a; O'Brien et al., 2006; Sayers and Newton, 2006; Feldmann et al., 2007; Pabari et al., 2011; Iwasaki et al., 2013; Shahrani et al., 2015). However, including multiple aspects such as expectations and experience (Feldmann et al., 2007) or expectations and satisfaction (Shahrani et al., 2015) in the same questionnaire may cause a problem of difficulty in implementing the questionnaire at different time periods. The set of questionnaires presented here were designed to assess patient expectations, experiences, and satisfaction through a course of treatment at the most appropriate time in order to avoid this problem. Although these questionnaires were originally designed for orthodontic patients with different appliances, they were comprehensive in their contents, so they were regarded as a good baseline to start with and to be refined and modified in order to be used for orthodontic patients with fixed appliances. This could allow them to be used in clinical trials with fixed appliances.

When comparing the Pre-treatment Questionnaire with a previously developed questionnaire by Sayers and Newton (2006), the latter mainly focused on the

measurement of 12 to 14 years old patient and parent expectations of orthodontic treatment. The Pre-treatment Questionnaire in this study measures patient expectations and their motivation for seeking treatment, which could be beneficial in identifying patient needs during treatment without extraneous influence and also aligns to the Post-treatment Questionnaire presented here.

With regard to the validation methods, some studies have depended solely on face validity (Bennett et al., 1997; Bennett et al., 2001; Sayers and Newton, 2006; Feldmann et al., 2007; Shahrani et al., 2015), which may not be robust enough to fully assess the validity of questionnaires compared to content validity. Mandall et al. (2006a) assumed their developed questionnaire, measuring the impact of fixed appliance on daily life, as having a face and content validity, however, this was based only on the method of development without using any formal validity assessment.

3.1.8.5 Strengths of the Study

In order to allow future inferences to be easily derived from this study, all the efforts were applied to avoid the weaknesses of previous studies, particularly those relating to the quantification of content validity as highlighted by Haynes et al. (1995), Polit and Beck (2006), and DeVon et al. (2007). To overcome this, the recommendations provided by Polit and Beck (2006) were followed:

1. Acronyms of I-CVI and S-CVI were used to distinguish between the two types of content validity index.
2. A clear distinction between S-CVI/Ave and S-CVI/UA was presented and both methods were eventually calculated.
3. An exact value of I-CVI for each item as well as the S-CVI for the overall questionnaire was reported.

4. All the relevant and retained items and the final versions of questionnaires achieved the minimum acceptable values of I-CVI, S-CVI/Ave, and S-CVI/UA (Lynn, 1986; Davis, 1992; Waltz et al., 2005; Polit and Beck, 2006; Polit et al., 2007).
5. Clear constructs, domains, and instructions were provided to the experts (Lynn, 1986; Grant and Davis, 1997; Polit and Beck, 2006).
6. Two rounds of validation were applied (Lynn, 1986; Haynes et al., 1995; Rubio et al., 2003; Polit et al., 2007).
7. In both rounds, a heterogeneous panel (patients, postgraduate students and specialist orthodontists) was participated in order to provide a more thorough assessment of the content and face validity. Patients were involved in both stages of validation and were considered as “experiential experts”.
8. The impact of this work is that a series of three valid and reliable questionnaires have been developed that are concise and suitable for assessing patient perceptions at different stages of fixed appliance orthodontic treatment by all age groups.

3.1.8.6 Limitations of the Study

1. The patient sample for this study was collected from a single university clinic and from one city within the UK and this could potentially affect the generalisability of the results.
2. Content validity could include bias across the experts as their feedback is subjective (Nunnally and Bernstein, 1994; Rubio et al., 2003; Zamanzadeh et al., 2015). Additionally, any unintentionally omitted content might not be tested even though experts were asked to provide their suggestions and indicate if any important aspects had been missed.
3. For the reliability assessment, some limitations were indicated because of difficulty in obtaining an appropriate number of recently started and finished patients. Therefore, the data were obtained from previous patients who completed the

questionnaires during the clinical trial and consequently the items that were added after validation were not included in the reliability test. However, these were only one item in the Pre-treatment Questionnaire and two items in the Post-treatment Questionnaire.

Future work could investigate if further modifications of the questionnaires are required to be valid for other ethnic groups and to convert them to other languages.

3.1.9 Conclusions

1. Three content valid and reliable (internally consistent) questionnaires have been developed for the evaluation of patient expectations, experiences, and the impact of treatment with fixed orthodontic appliances.
2. Based on the results of face and content validity undertaken in this study, face validity alone is not robust enough to demonstrate validity of questionnaire for use in this area.
3. This study has demonstrated the importance of both quantitative and qualitative methods in the assessment of validity.

This study has been published in the European Journal of orthodontics (Yassir et al., 2017a)

3.2 VARIATION IN BRACKET SLOT SIZES AND PRESCRIPTIONS USED BY SPECIALIST ORTHODONTISTS IN THE UNITED KINGDOM: UK NATIONAL SURVEY

3.2.1 History of Contemporary Fixed Orthodontic Appliances

At the end of the 19th century, pioneers of orthodontics including Angle, Kingsley, and Farrar designed appliances, which are regarded as the beginning of the contemporary fixed orthodontic appliances (Cash et al., 2004).

Contemporary fixed orthodontic appliances, with a few exceptions, are based on Edward Angle's edgewise appliance developed in the early 20th century. Angle developed four major appliance systems: E-arch; pin and tube; ribbon arch; and the edgewise appliance. In his edgewise appliance, Angle reoriented the slot horizontally rather than vertically compared to the ribbon arch (Proffit et al., 2013). The slot size of the brackets was 0.022-inch by 0.028-inch and the wires were constructed from gold alloy and sometimes with platinum or silver alloy. In the 1930s, a cheaper and stiffer alloy of chromium steel called "stainless steel" was introduced as an orthodontic material. The clinicians were tempted soon to replace the precious alloy with stainless steel, however many of them were worried about the higher force that would be generated from the stainless steel wires and their possible damaging effect on the oral tissues (Peck, 2001; Cash et al., 2004). The capability of these wires to generate similar forces to that of the gold wires with smaller dimensions made it logical to decrease the slot size from 0.022 × 0.028-inch to 0.018 × 0.022-inch (Rubin, 2001; Peck, 2001; Kusy, 2002).

The introduction of nickel-titanium alloy archwires in the 1970s was an interesting advance in metallurgical technology since these wires could be considered comparable to gold wires in their stiffness with less cost and thus clinicians returned to the 0.022-inch bracket slot (Rubin, 2001; El-Angbawi, 2013).

Currently, both 0.018-inch and 0.022-inch bracket systems are used all over the world and the factor that favours one over the other mostly depends on the preference of the clinician, since no prospective study has investigated the clinical differences between the two systems.

3.2.2 Development of Brackets

In 1928 in an attempt to overcome the weakness of the ribbon arch, Angle developed the edgewise bracket where he rotated the slot 90 degrees to be horizontal and used a rectangular archwire to provide better control of both the crown and root. However, this required skilful wire bending and consequently greater chair-side time. These reasons in addition to the exclusive dependence on a non-extraction technique encouraged Raymond Begg to adopt an alternative treatment philosophy. The Begg bracket system was an upside down version of the ribbon arch and he replaced the precious wires with light stainless steel wires of 0.016-inch. The Begg appliance was the appliance of choice especially in the 1960s, because of the ability to produce more efficient results with less clinical effort. With time the contemporary edgewise brackets based on the rectangular horizontal slot and rectangular archwires have developed and these superseded the Begg system again (Proffit et al., 2013).

In 1972, Andrews introduced the Straight-Wire Appliance™, which was an important milestone in orthodontic bracket design, since these brackets were manufactured with built-in tip (angulation), torque (inclination), and in-out movements for each tooth. This development reduced the necessity for wire bending and hence reduced chairside time.

The bracket design was derived from Andrews' "six keys" to normal occlusion, which had been obtained from the measurement of 120 non-orthodontic normal subjects with a pleasant appearance and correct occlusion (Andrews, 1972; Andrews, 1976a; Thickett et al., 2007).

This evolution in bracket design allowed Andrews and others to produce more diversity in brackets according to individual clinical situations. For example, Andrews introduced three different prescriptions of incisor bracket torque. Additionally, he produced brackets for extractions and non-extraction cases, where anti-tip and anti-rotation were incorporated in the bracket design of extraction cases to avoid the tip and rotation of the buccal surface toward the extraction site (Andrews, 1976b; Thickett et al., 2007).

Roth (1976) was worried about the difficulties of multiple bracket systems, so he produced his prescription of pre-adjusted edgewise brackets in an attempt to be applicable for most cases. In this prescription, he modified and decreased the variations of Andrews' prescriptions. Roth's prescription was regarded as the second generation of pre-adjusted bracket system and characterised by:

- Increasing tip and torque in the maxillary incisors;
- Increasing distal tip in the canine brackets to assist canine guidance;
- Adding distal crown tip on lower buccal segments to accommodate greater anchorage demands; and
- Increasing torque in upper molars to avoid dropping of palatal cusps (Roth, 1976; Roth, 1987; Thickett et al., 2007).

The third generation of pre-adjusted bracket system was produced by McLaughlin, Bennett, and Trevisi (MBT). They modified the Andrews' prescription as follows (Thickett et al., 2007; McLaughlin et al., 2001):

- Decreased tip for the anterior teeth, to reduce the strain on molar anchorage and to avoid an arch length increase during treatment, as well as to avoid the risk of close proximity of canine and premolar roots;
- Decreased tip for upper posterior teeth to reduce the anchorage demands;
- Increased torque for the incisors and molars; and
- Made three canine torque prescriptions available (-7, 0, and +7 degrees) depending on the case need.

Nowadays, both Roth and MBT systems are the most widely used by clinicians, however further prescriptions are also available. Andrews, Roth, and MBT prescriptions are illustrated in table 34 and 35.

Table 34: Tip prescriptions (degrees) for different pre-adjusted edgewise bracket systems (Thickett et al., 2007)

Teeth		1	2	3	4	5	6	7
Upper	MBT	4	8	8	0	0	0	0
	Roth	5	9	13	0	0	0	0
	Andrews	5	9	11	2	2	5	5
Lower	Andrews	2	2	5	2	2	2	2
	Roth	2	2	7	-1	-1	-1	-1
	MBT	4	8	8	0	0	0	0

Table 35: Torque prescriptions (degrees) in different pre-adjusted edgewise bracket systems (Thickett et al., 2007)

Teeth		1	2	3	4	5	6	7
Upper	MBT	17	10	-7	-7	-7	-14	-14
	Roth	12	8	-2	-7	-7	-14	-14
	Andrews	7	3	-7	-7	-7	-9	-9
Lower	Andrews	-1	-1	-11	-17	-22	-30	-33
	Roth	-1	-1	-11	-17	-22	-30	-30
	MBT	-6	-6	-6	-12	-17	-20	-10

3.2.3 Clinician Preference

Different types of bracket slots (0.018-inch and 0.022-inch) and prescriptions (Andrews, Roth, MBT, or others) are used in clinical practice and it is difficult to find any logical reason for specific selection since there is no published scientific evidence to support one over any of the others.

Keim and his colleagues have conducted a series of comprehensive surveys in the United States on orthodontic diagnosis and treatment procedures since 1986. In 2002 and 2008 they reported that the response rate was 9.0% and 7.7 %, respectively. They mentioned that in spite of this low response rate, the results could be considered valid due to the consistency of answers and demographic data. Their results showed that the Roth prescription was the most commonly used brackets in 2002 (55.9%) and 2008 (44.8%) among all other bracket prescriptions, while this percentage had decreased to be the third commonly used brackets in 2014 (31.0%). On the other hand, the MBT prescription brackets were only representing 6.6% of the bracket usage in 2002 and then increased to 19.6% in 2008 until it became the most commonly used brackets in 2014 (41.0%). This revealed the increase in acceptance and popularity of MBT prescription over time since its introduction. Interestingly, the standard edgewise brackets represented the second commonly used brackets among other types of brackets in these three surveys; 2002 (48.0%), 2008 (23.4%), and 2014 (32.0%). Regarding bracket slot systems, the 0.018-inch slot showed a drop in the use from 49.3% in 1986 to 25.0% in 2014. On the other hand, the use of the 0.022-inch slot had increased from 50.7% in 1986 to 70.0% in 2014 (Keim et al., 2002a, 2008a, and 2014a).

Another interesting finding from Keim et al. surveys was that older practitioners were more likely to use the Roth prescription and 0.018-inch slot brackets, whereas younger

practitioners more commonly used the MBT prescription and 0.022-inch slot brackets (Keim et al., 2002b, 2008b, and 2014b).

It is worth mentioning that the 0.022-inch slot brackets had a higher percentage of use than the 0.018-inch slot brackets throughout the surveys (1986, 1990, 1996, 2002, 2008, and 2014) and with different bracket prescriptions (MBT, Roth, Damon, and other) (Keim et al., 2002a, 2008a, 2014a, and 2014c).

A survey undertaken in the United Kingdom by Banks et al. (2010) was considered by the authors as the first published data in the UK that documents orthodontic clinical practice. The questionnaire was posted to 935 specialists and the response rate was 66.3%. The study included a variety of settings such as hospital based practitioners (NHS and academic consultants, associate specialists, and staff grades), specialist practitioners, and community specialists, with varying degrees of experience (0-10, 11-20, 21-30, and 30+ years post orthodontic qualification) and from six different geographic regions in the UK. The results revealed that UK respondents expressed a preference for the MBT bracket prescription (46.9%) followed by Roth (41.0%) and only a few of the respondents used the Andrews prescription (9.0%). In regard to slot size, the overwhelming preference was for 0.022-inch (91.2%).

It is interesting to note in the survey of Banks et al. that the higher percentages of 0.018-inch slot bracket users were the community group clinicians (24.1%), private only clinicians (23.1%), clinicians in Northern Ireland (17.9%) and Scotland (17.6%). Regarding the influence of clinicians' experience on their preference, the most senior clinicians (30+ years qualification) preferred the 0.018-inch bracket slot, while the recently qualified clinicians tend to use the 0.022-inch slot and MBT prescription. This comes in accordance with the findings of Keim et al. (2002b, 2008b, and 2014b) and might in part reflect that senior orthodontists try to maintain traditional methods of

treatment, whilst on the other hand recently qualified orthodontists prefer to use new techniques of treatment. The explanation of that could be due to the effect of training and this is also noticeable within the survey by Banks et al. (2010), where younger specialists preferred light-cure bonding technique in comparison to senior clinicians. In regard to the distribution of bracket prescriptions, the study reflected a variation in different geographic areas, such as the MBT prescription being more popular in routine use in Scotland, Northern Ireland, and Midlands (which showed preference of MBT versus Roth and Andrews prescriptions), whereas Roth is the commonly used prescription in Wales. Northern and Southern England showed almost the same preference between Roth and MBT prescriptions (Table 36).

Although the survey by Banks et al. (2010) was not considered completely comprehensive when compared to the surveys by Keim et al., it is more generalisable as it had a higher response rate. All these surveys revealed that the 0.022-inch slot brackets are the most routinely used. This was at variance with the claim of Rubin (2001), who stated the slight majority of US clinicians use 0.022-inch slot, while the vast majority in Europe use the 0.018-inch slot. For pre-adjusted brackets, both the US and UK orthodontists showed a recent preference to use the MBT prescription brackets. Standard edgewise brackets system are very rarely used in the UK (2.8%), but it was the second preference for the specialists in the US.

McNamara et al. (2010), in their study to discover clinicians' choices with respect to archwires selection in southern England, used a questionnaire which achieved a very high response rate of 92.6%. They found that 99% of the respondents prefer the 0.022-inch bracket slot. This result was close to the finding by Banks et al. (2010). However, the number of orthodontists who participated in the study was lower (100).

Historically, the standard edgewise bracket was manufactured with no pre-adjusted prescription, with wire bending being necessary to achieve ideal tooth alignment. The 0.016 × 0.022-inch stainless steel archwire as a working archwire for the 0.018-inch slot bracket is easier to bend and produces lighter forces than the 0.019 × 0.025-inch stainless steel working archwire for the 0.022-inch slot brackets, so this could explain the historical preference for 0.018-inch slot brackets to avoid any unwanted high forces. With the development of pre-adjusted appliance systems, the need for wire bending reduced and the advent of sliding mechanics for tooth movement developed. The size and stiffness of the 0.019 × 0.025-inch wire with the 0.022-inch slot bracket might achieve better control of tooth movement with less deflection and binding especially during space closure with sliding mechanics (McLaughlin et al., 2001). This could explain the increased use in recent years. However, there is no scientific support for this preference.

Previous studies have reflected the preference and distribution of the bracket slot size and prescription in the United States of America and the United Kingdom, but what about the bracket distribution in the rest of the world's countries or regions?

Rubin (2001) emphasised the importance of adopting a single bracket slot size, as this would standardise the treatment technique and ensure the same treatment service for transfer cases without any confusion or prolonged time for changing brackets. For that reason, he suggested a 0.020-inch slot as a suitable alternative for the 0.018-inch and 0.022-inch slot brackets. He developed a questionnaire and sent it to the chairs of the orthodontic departments in the US hoping that his idea would convince them. The responses were disappointing because only 12 were in favour whereas 17 refused to support the idea, so he could not progress this thought.

Later in the same year (2001), Peck welcomed Rubin's idea and he stated that it would be more rationale to consolidate the two bracket systems with one new standardised slot size, which would preferably be somewhere between them and with metric dimensions, such as 0.55 mm (0.02165-inch) or 0.50 mm (0.01969-inch) and he suggested a 0.55 × 0.70 mm (0.02165 × 0.02756-inch) edgewise slot as it would make the shift from both existing systems to this new system straightforward (Peck, 2001). In agreement with these ideas, Kusy (2002) supported the use of single alternative brackets with a mean slot size of 0.51mm (0.02008-inch).

Taking the globalisation of one standard bracket system into consideration, Epstein in 2002 reintroduced the idea of amalgamation of the two bracket slot sizes within one appliance. This was firstly proposed by Schudy and Scudy (1975) and then by Gianelly et al. (1985). Epstein suggested using 0.018-inch brackets on the central and lateral incisors and 0.022-inch brackets on canines and posterior teeth. This hybrid appliance would provide a more efficient and free sliding movement of teeth with reduced friction during canine retraction, anterior retraction, or posterior protraction with simultaneous anterior torque control (Epstein, 2002).

Unless any evidence is produced to determine the greater effectiveness of one bracket slot size when compared to the other, further debate regarding the rationale of using two systems without any changes in clinical practice will continue.

Table 36: Percentage routine use of different bracket systems in the UK (Banks et al., 2010)

	Andrews	**Roth**	**MBT**	**0.018-inch**	**0.022-inch**
Hospital	10.2%	37.2%	50.9%	4.0%	96.0%
Practice (all)	8.2%	41.1%	46.6%	10.6%	90.3%
NHS only	13.0%	37.0%	42.6%	11.1%	87.0%
Private only	11.5%	23.1%	50.0%	23.1%	84.6%
Community	10.3%	62.1%	27.6%	24.1%	82.8%
Qualified, 10 years	4.7%	34.7%	56.3%	5.2%	96.2%
Qualified, 11-20 years	8.5%	40.1%	48.3%	6.6%	78.4%
Qualified, 21-30 years	14.5%	50.0%	37.7%	9.4%	88.0%
Qualified, 30+ years	5.7%	47.1%	34.3%	24.3%	75.3%
North	5.8%	44.2%	47.7%	3.8%	96.2%
South	9.3%	44.5%	44.8%	7.8%	93.2%
Midlands	20.5%	25.6%	51.3%	10.2%	92.3%
Wales	0.0%	57.1%	47.6%	14.3%	90.4%
Scotland	3.9%	29.4%	68.6%	17.6%	90.2%
Northern Ireland	14.3%	28.6%	60.7%	17.9%	85.7%
All	**9.0**%	**41.0**%	**46.9**%	**8.8**%	**91.2**%

Table 37: Summary of surveys concerning orthodontic clinical practice

Study	Year	Setting	Sample	Study Design	Response Rate	0.018-inch	0.022-inch	MBT	ROTH	Andrews	Standard Edgewise
Keim et al.	2002a	US	789	Posted Questionnaire	9.0%	40.5%	54.2%	6.6%	55.9%	7.3%	48.0%
Keim et al.	2008a	US	808	Posted Questionnaire	7.7%	32.4%	62.8%	19.6%	44.8%	3.0%	23.4%
Keim et al.	2014a	US	209	e-mail Questionnaire	1.9%	25.0%	70.0%	41.0%	31.0%	2.0%	32.0%
Banks et al.	2010	UK	935	Posted Questionnaire	66.3%	8.8%	91.2%	46.9%	41.0%	9.0%	2.8%
McNamara et al.	2010	South England	108	Personally-handled Questionnaire and a Follow-up Telephone call	92.6%	1%	99%	NA	NA	NA	NA

3.2.4 Aim of the Survey

The aim of this survey was to investigate the trends within routine orthodontic practice regarding the use and reasons for selecting particular bracket slot and the variation in prescriptions among specialist orthodontists throughout the United Kingdom.

3.2.5 Method of Investigation

The survey was designed by the investigator (Yassir A. Yassir), to find out the distribution of bracket slots and prescriptions used in routine orthodontic practice throughout the UK. The reason for undertaking this assessment of bracket slot distribution in the UK was considered important in relation to interpreting the results of the current clinical trial comparing the outcomes of 0.018-inch and 0.022-inch slot brackets.

The survey was anonymous and sent to the Chair of the audit committee of the British Orthodontic Society (BOS) for consideration. Following approval, the online survey was circulated in April 2015 to all 978 email addresses of the Consultant Orthodontists Group and Orthodontic Specialists Group (registered on the UK Specialist List for Orthodontics), with an explanation of the nature of the survey and inviting them to participate (Appendix 18). In order to maximise the response rate, two email reminders were sent via the BOS in June and July 2015.

3.2.5.1 Survey Design

The survey was divided into seven questions as follows:

1. ***Location of practice:*** the answer options were subdivided according to the main geographic regions within the UK; North of England, Midlands, South of England, Scotland, Wales, and Northern Ireland.
2. ***Number of years in orthodontic practice:*** the answer options were subdivided into four categories; 1-10, 11-20, 21-30, and 30+ years.
3. ***Specialist List for Orthodontics:*** the answer options determined whether the participant was registered on the UK Specialist List for Orthodontics or not.
4. ***Bracket prescription:*** this question reflected the orthodontist's preference for bracket prescription. The answer options were; Roth, MBT, and other.
5. ***Bracket slot size:*** this question identified the bracket slot size routinely used by the orthodontist. The answer options were; 0.018-inch and 0.022-inch slots.
6. ***Reason for use of the bracket slot size:*** this question was designed to determine the reason for using the specific bracket slot. The answer options were; shorter treatment time, better outcomes e.g. overbite/torque control, ease of wire bending, reduced biological side effects, and the last option was an open-ended question "other (please specify)" in case there is an additional reason not mentioned in the list.
7. ***Proportion of conventional versus self-ligating cases:*** this question was designed to identify the percentages of conventional versus self-ligating cases undertaken and the answers were ranged from 0% conventional/100% self-ligating to 100% conventional/0% self-ligating.

3.2.5.2 Statistical Analysis

The data were analysed using the Statistical Package for Social Sciences for Windows, version 22.0 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics and percentages were calculated for the whole survey. Chi-square analyses were used to determine the statistical differences in the use of bracket slots and prescriptions according to the regions and years of experience.

3.2.6 Results

In October 2015 and three months following the second reminder, to give participants the opportunity to respond, the data were collected. The total number of respondents was 305, which represents 31.2% of the of BOS specialist orthodontic members.

3.2.6.1 Location of Practice

Most of the respondents were from the South of England (45.1%) followed by respondents from the North of England (22.7%), Midlands (13.5%), Scotland (10.5%), Wales (4.3%), and Northern Ireland (3.9%) (Table 38, Figure 3). The total number of respondents that answered this question was 304, while one failed to answer this.

Table 38: Location of practice of the respondents

Answer Options	Response Percent	Response Count
North of England	22.7%	69
Midlands	13.5%	41
South of England	45.1%	137
Scotland	10.5%	32
Wales	4.3%	13
Northern Ireland	3.9%	12
Answered Questions		**304**
Unanswered Questions		**1**

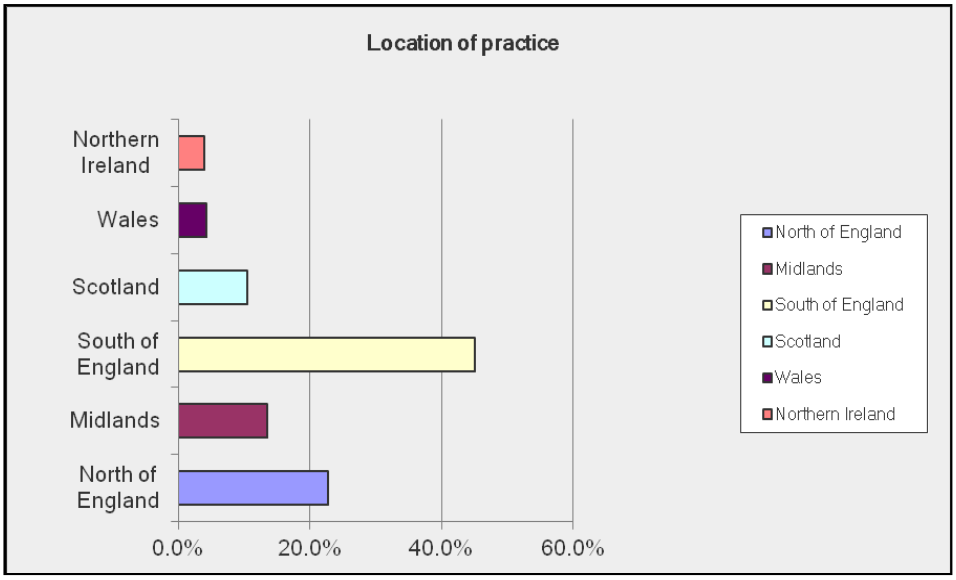

Figure 3: Bar chart showing location of practice of the respondents

3.2.6.2 Number of Years in Orthodontic Practice

Orthodontists with 11-20 years of orthodontic practice represented the highest percentage of respondents (36.4%), followed by orthodontists with 21-30 years (25.9%), 1-10 years (20.0%), and 30+ years of practice (17.7%). All the 305 respondents answered this question (Table 39).

Table 39: Number of years in orthodontic practice of the respondents

Answer Options	Response Percent	Response Count
1-10	20.0%	61
11-20	36.4%	111
21-30	25.9%	79
30+	17.7%	54
Answered Questions		**305**
Unanswered Questions		**0**

3.2.6.3 Specialist List for Orthodontics

All the 305 respondents (100%) confirmed they were registered as specialist orthodontists (Table 40).

Table 40: Specialist list for orthodontics

Answer Options	Response Percent	Response Count
Yes	100%	305
No	0.0%	0
Answered Questions		**305**
Unanswered Questions		**0**

3.2.6.4 Bracket Prescription

The survey revealed that 81.6% of the respondents used the MBT prescription, while the Roth prescription represented 14.1% and other prescriptions accounted for 4.3% of routine practice use. No respondent failed to answer this question (Table 41).

Table 41: Percentages of bracket prescriptions use

Answer Options	Response Percent	Response Count
Roth	14.1%	43
MBT	81.6%	249
Other	4.3%	13
Answered Questions		**305**
Unanswered Questions		**0**

3.2.6.5 Bracket Slot Size

The vast majority of the respondents (98.7%) used the 0.022-inch slot bracket, whereas only four respondents (1.3%) used a 0.018-inch slot bracket system. Two respondents did not answer this question (Table 42).

Table 42: Percentages of bracket slot sizes use

Answer Options	Response Percent	Response Count
0.018’’	1.3%	4
0.022’’	98.7%	299
Answered Questions		**303**
Unanswered Questions		**2**

3.2.6.6 Rationale for Bracket Slot Size Use

More than half of the respondents (59.5%) reported that they used a particular bracket slot because of perceived improved outcomes e.g. overbite/torque control. From this percentage, only one was a user of the 0.018-inch slot, while the 0.022-inch slot users were 178 orthodontists. Ease of wire bending was a reason for using the 0.022-inch slot systems for 4.3% of the respondents. A reduction in biological side effects was a reason for 3.7% of respondents. Of these, three respondents were users of the 0.018-inch slot and eight respondents were 0.022-inch slot users. Shorter treatment time was only a reason for using 0.022-inch slot bracket by one respondent (0.3%) (Table 43). Ninety seven respondents who used 0.022-inch slot brackets, comprising 32.2%, chose the "other reason" option which is an open-ended question, thereby their answers were collected and categorised into four main reasons (Table 44). The most common reason was "Taught and Trained" and it represented 56.7% of the answers. The second group of answers was categorised as "Better Control" and represented 27.8%. Ten of the respondents (10.3%) used the 0.022-inch slot because there was no other option available in their workplace, so they were categorised as "No Choice". While 5.2% did not specify their reason when they chose the "other reason" option and thus they were categorised as "No Specific Reason" (Appendix 19). Four respondents did not answer this question.

Table 43: Reasons for using particular bracket slot size by the respondents

Answer Options	Response Percent	Response Count
Shorter treatment time	0.3%	1
Better outcomes e.g. overbite/torque control	59.5%	179
Ease of wire bending	4.3%	13
Reduced biological side effects	3.7%	11
Other (please specify)	32.2%	97
Answered Questions		**301**
Unanswered Questions		**4**

Table 44: Other reasons for using bracket slot size by the respondents

Answer Options	Response Percent	Response Count
Taught and Trained	56.7%	55
Better Control	27.8%	27
No Choice	10.3%	10
No Specific Reason	5.2%	5
Answered Question		**97**

3.2.6.7 Proportion of Conventional Versus Self-Ligating Brackets

The majority of the respondents reported either 100% (47.5%) or 90% (33.8%) use of conventional brackets. A smaller group (2.3% and 2.0%, respectively) of the respondents used 100% and 75% self-ligating brackets (Table 45).

Table 45: Proportion of conventional/self-ligating brackets use

Answer Options	Response Percent	Response Count
0% Conventional/100% Self-ligating	2.3%	7
10%	1.6%	5
25%	2.0%	6
50%	1.6%	5
75%	11.1%	34
90%	33.8%	103
100% Conventional/0% Self-ligating	47.5%	145
Answered Questions		**305**
Unanswered Questions		**0**

3.2.6.8 Distribution of Bracket Slot Size According to Location of Practice

According to the result of this survey, the number of users of 0.022-inch slot bracket system was significantly higher in all the regions of UK than users of 0.018-inch slot bracket system. Orthodontists who used the 0.018-inch slot were two in South of England, one in Midlands, and one in Scotland (Table 46).

Table 46: Distribution of bracket slot size according to location of practice

Answer Options	0.018’’%	0.018’’	0.022’’%	0.022’’	Response Percent	Response Count
North of England	0.0%	0	22.5%	68	22.5%	68
Midlands	0.3%	1	13.3%	40	13.6%	41
South of England	0.6%	2	44.4%	134	45.0%	136
Scotland	0.3%	1	10.3%	31	10.6%	32
Wales	0.0%	0	4.3%	13	4.3%	13
Northern Ireland	0.0%	0	4.0%	12	4.0%	12
Answered Questions						**302**
Unanswered Questions						**1**

3.2.6.9 Distribution of Bracket Slot Size According to Years of Orthodontic Practice

Once more there was significantly higher number of orthodontists using a 0.022-inch slot system compared to those using 0.018-inch slot brackets in all categories of orthodontic experience. The users of 0.018-inch slots were divided as two respondents with 11-20 years and two with 30+ years of orthodontic practice (Table 47).

Table 47: Distribution of bracket slot size according to years of practice

Answer Options	0.018’’%	0.018’’	0.022’’%	0.022’’	Response Percent	Response Count
1-10	0.0%	0	20.1%	61	20.1%	61
11-20	0.7%	2	35.6%	108	36.3%	110
21-30	0.0%	0	25.7%	78	25.7%	78
30+	0.7%	2	17.1%	52	17.8%	54
Answered Questions						**303**
Unanswered Questions						**0**

3.2.6.10 Distribution of Bracket Slot Size According to Bracket Prescription

The results showed that three of the 0.018-inch slot bracket users (1.0%) used the MBT bracket prescription, while only one (0.3%) used the Roth prescription. There were no respondents in the “other bracket prescription” users group who preferred the 0.018-inch slot system. All other respondents used 0.022-inch slot bracket; 80.8% MBT, 13.5% Roth, 4.3% other prescriptions (Table 48).

Table 48: Distribution of bracket slot size according bracket prescriptions

Answer Options	0.018''%	0.018''	0.022''%	0.022''	Response Percent	Response Count
Roth	0.3%	1	13.5%	41	13.9%	42
MBT	1.0%	3	80.8%	245	81.8%	248
Other	0.0%	0	4.3%	13	4.3%	13
Answered Questions						**303**
Unanswered Questions						**0**

3.2.6.11 Distribution of Bracket Prescription According to Location of Practice

In all the six regions within the UK the MBT system was the dominant prescription used by the respondents compared to the Roth and other prescriptions. The highest percentages of Roth and other prescriptions users were in the South of England (Table 49, Figure 4).

Table 49: Distribution of bracket prescription according to location of practice

Answer Options	Roth %	Roth	MBT %	MBT	Other %	Other	Response Percent	Response Count
North of England	4.3%	13	18.1%	55	0.3%	1	22.7%	69
Midlands	1.6%	5	11.5%	35	0.3%	1	13.5%	41
South of England	7.2%	22	34.9%	106	3.0%	9	45.1%	137
Scotland	0.7%	2	9.5%	29	0.3%	1	10.5%	32
Wales	0.0%	0	4.0%	12	0.3%	1	4.3%	13
Northern Ireland	0.3%	1	3.6%	11	0.0%	0	3.9%	12
Answered Questions								**304**
Unanswered Questions								**1**

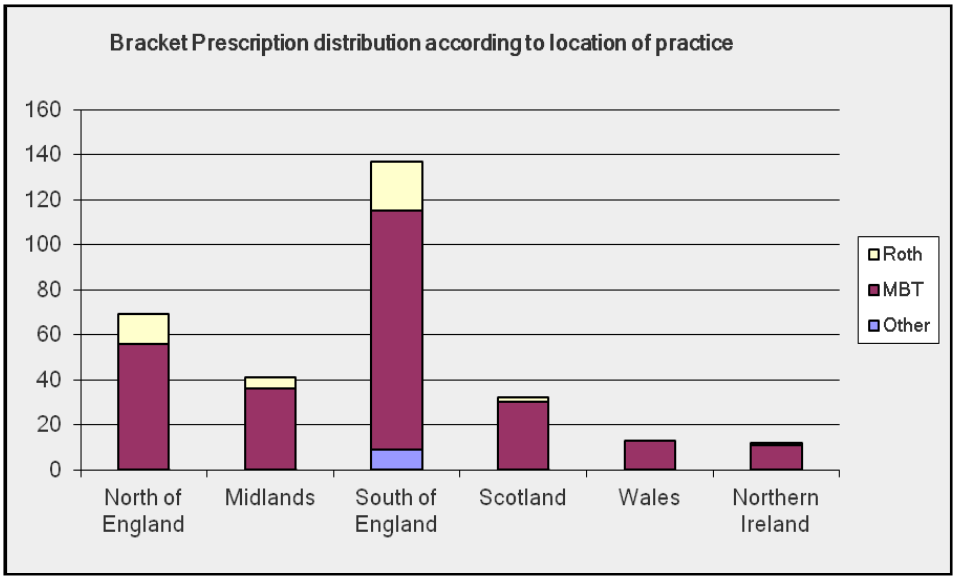

Figure 4: Bar chart showing distribution of bracket prescription according to location of practice

3.2.6.12 Distribution of Bracket Prescription According to Years of Orthodontic Practice

The MBT prescription had the highest percentages of users in all categories of orthodontic experience (11-20, 21-30, 1-10, and 30+ years, respectively). The highest percentage of Roth users was in the 21-30 years of experience group followed by 11-20 years, 30+ years, and 1-10 years groups, respectively. While other prescriptions were used mainly by orthodontists who had 30+ years of experience (Table 50, Figure 5).

Table 50: Distribution of bracket prescription according to years of practice

Answer Options	Roth %	Roth	MBT %	MBT	Other %	Other	Response Percent	Response Count
1-10	1.3%	4	18.0%	55	0.7%	2	20.0%	61
11-20	4.3%	13	31.1%	95	1.0%	3	36.4%	111
21-30	5.6%	17	20.0%	61	0.3%	1	25.9%	79
30+	3.0%	9	12.5%	38	2.3%	7	17.7%	54
Answered Questions								**305**
Unanswered Questions								**0**

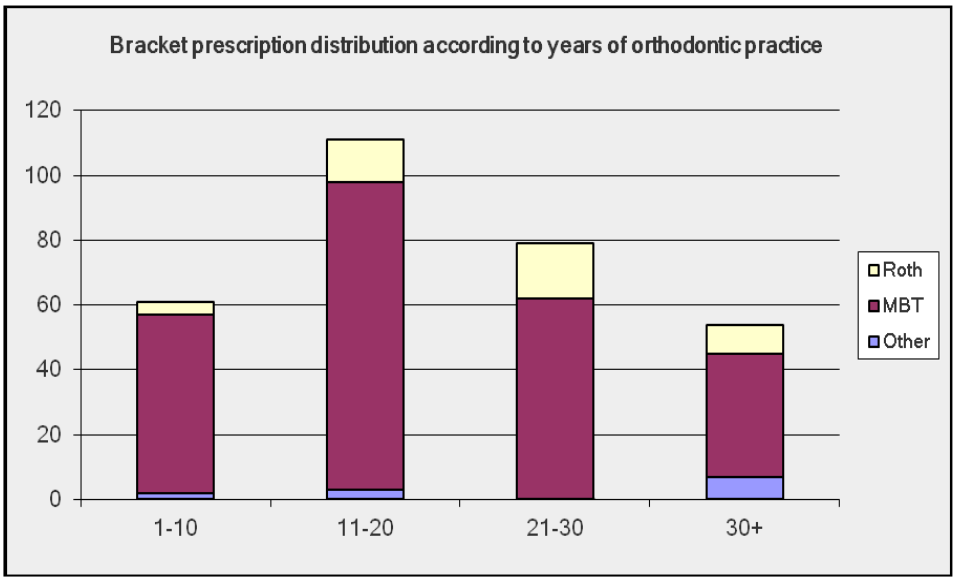

Figure 5: Bar chart showing distribution of bracket prescription according to years of practice

Statistically significant higher percentages of the 0.022-inch slot and MBT bracket systems in different locations of practice and years of experience were found.

3.2.7 Discussion

This survey was conducted to provide a current view of the clinical trends of UK orthodontists and to be as an adjunct to the present RCT comparing the effectiveness of different slot size of orthodontic brackets. The survey was designed by the principal investigator (Y.A.Y.), reviewed by the supervisors and approved by the audit committee of the BOS. Although it was intended to be simple and short with two reminders being sent by the BOS to increase the response rate, this was still relatively low (31.2%) compared to other UK studies, i.e. Banks et al. (2010) (66.3%) and McNamara et al. (2010) (92.6%). Nevertheless, the response rate was higher than that by Keim et al. (2002a, 2008a, and 2014a) in the US with response rates of 9.0%, 7.7%, and 1.9%, respectively. This may be related to the difference in the method of administration and the number of included sample. Keim et al. (2002a, 2008a, and 2014a) and Banks et al. (2010) sent their survey by post to 8,812; 10,523; 10,688 and 935 specialist

practitioners, respectively. The total number of the UK sample in the survey by Banks et al. (2010) was comparable to that of the current survey (978). On the other hand in the other UK survey by McNamara et al. (2010), the questionnaires were personally handed to only 108 clinicians (17 of them were dentists with special interest in orthodontics) and followed by telephone calls to those who did not respond and this could explain the high percentage response rate in the study. The current survey was sent as an email which might be easily overlooked by the respondents and this in turn potentially reduced the response rate.

The pattern of response rate from the highest was; South of England, North of England, Midlands, Scotland, Wales, and Northern Ireland. The pattern in the survey by Banks et al. (2010) was; South of England, North of England, Scotland, Midlands, Northern Ireland, and Wales. These patterns were comparable and might reflect the distribution of orthodontists within the UK. All the respondents in the current survey were specialist orthodontists and the highest proportion had 11-20 years of experience (36.4%), while the lowest had been working for 30+ years (17.7%).

The results revealed that the most popular bracket prescription in routine use is the MBT (81.6%) followed by Roth (14.1%) and other prescriptions (4.3%). This finding was in contrast to that by Keim et al. (2002a and 2008a) where they found the most commonly used brackets in the US were Roth prescription followed by standard edgewise brackets, while MBT prescription was only 6.6% in 2002 and 19.6% in 2008. However, the results were in line with the recent survey by Keim et al. (2014a) where the MBT became the predominant prescription used in the US (41.0%) followed by standard edgewise (32.0%), whereas Roth was (31.0%). Likewise, this survey was in agreement with the UK survey by Banks et al. (2010) who found that the MBT prescription was the most popular in use (46.9%) closely followed by Roth (41.0%),

whilst Andrews (9.0%) and other prescriptions (3.4%) were in the minority. Nevertheless, the percentage of MBT brackets in the survey by Banks et al. was close to that of Roth prescription, which is unlike the current survey where the difference between them is considerable. This would indicate that MBT system usage is increasing since it was introduced.

Regarding bracket slot size, it has been found that 98.7% of the respondents used the 0.022-inch slot and only 1.3% used the 0.018-inch slot (4 from 303 respondents, as 2 did not answer this question). The users of the 0.018-inch slot were two from the South of England, one from Midlands, and one from Scotland. The previous surveys in the US also found the same trend but with different percentages (Keim et al., 2002a, 2008a, and 2014a). The percentages of using 0.022-inch slot brackets in the UK surveys were 91.2% (Banks et al., 2010) and 99.0% (McNamara et al., 2010). The latter is similar to the result of the current survey. The reasons for using a particular bracket slot size (which were mainly for the 0.022-inch slot) were as follows:

- ***Better outcomes*** *e.g. overbite/torque* (179 respondents): this was the most common reason for using 0.022-inch slot brackets (178 respondents). Only one of the 0.018-inch slot bracket users had selected this reason.
- ***Taught and trained*** (55 respondents): where the orthodontists said that they trained to use the 0.022-inch slot and they did not use the 0.018-inch slot brackets, so they were familiar with the 0.022-inch slot or they did not find a reason to change.
- ***Better control*** (27 respondents): the respondents considered the 0.022-inch slot brackets have better control in terms of rotation correction, arch form in three planes of space, expansion, overbite reduction, sliding mechanics, space closure, and slop control. Additionally, it is easier to add auxiliaries and there is a wider

range in wire selection e.g. flexible wires in the initial stages and rigid wires for surgical cases,

- ***Ease of wire bending*** (13 respondents): orthodontists who used the 0.022-inch slot brackets chose this option, however, this reason is illogical for the 0.022-inch slot brackets as the archwires used with 0.018-inch slot bracket systems are easier to bend.
- ***Reduced biological side effects*** (11 respondents): three of the orthodontists who used the 0.018-inch slot brackets selected the reduced biological side effects as a reason for their slot size choice which may be due to the lower number and lighter wire dimensions used in 0.018-inch compared to 0.022-inch slot brackets
- ***No choice*** for using different bracket slot (10 respondents): in this section, the orthodontists stated that only 0.022-inch slot brackets were available in their practice.
- ***No specific reason*** (5 respondents): the orthodontists who selected this option did not specify why they used 0.022-inch slot brackets or they were waiting for evidence to favour one slot against the other.
- ***Shorter treatment time*** (1 respondent): this was selected by one orthodontist as a reason for using the 0.022-inch slot bracket.

Despite the higher percentage preference for 0.022-inch slot bracket systems and the various reasons to justify the responses, some clinicians stated there is still insufficient evidence to support one system against the other, so they continued to use the system at their training institution or they had not found a convincing reason to change when only a 0.022-inch bracket system was available at work. Moreover, it is obvious from the results of this survey that teaching programmes and universities mainly use 0.022-inch slot bracket systems which results in their higher percentage of usage.

The survey also found that about half of the orthodontists who participated (47.5%) use conventional brackets and did not use self-ligating brackets. The percentage of orthodontists decreased as the proportion of using self-ligating brackets compared to conventional brackets increased. This is explainable by the fact that no scientifically-based evidence is available to favour one system against the other. Therefore, the clinicians also tend to maintain their "taught and trained" method of work.

3.2.7.1 Regional Variations

There was statistically significantly higher numbers of orthodontists who used the MBT and 0.022-inch slot brackets in all the six geographical regions of the UK. For bracket prescriptions, Banks et al. (2010) found the same results in the Midlands, Scotland, and Northern Ireland. Whereas, the use of MBT and Roth systems were comparable in the North and South of England and the Roth users were higher in Wales. This may reflect that the popularity of the relatively new prescription (MBT) is increasing noticeably with time. The considerably higher percentages of use of the 0.022-inch slot system in the same six regions were also found in the survey by Banks et al. (2010).

3.2.7.2 Influence of Years of Experience

Similarly, there were significantly higher numbers of orthodontists using the 0.022-inch slot brackets compared to the 0.018-inch slot in all categories of experience. This finding is in accordance with the findings of Banks et al. (2010) and Keim et al. (2002b, 2008b, and 2014b). The four users of the 0.018-inch slot were divided equally in the 11-20 and 30+ years groups of experience. Although the percentage of use of the Roth prescription increased with increasing years of experience (between 1 year and 30 years of experience), the MBT prescription showed overwhelming percentages in routine use for all levels of experience. Other prescriptions also showed the highest percentage of preference for clinicians with 30+ years of experience. This slightly disagreed with

previous surveys. Banks et al. (2010) mentioned that the most senior orthodontists tried to maintain their traditional way of training by using more 0.018-inch slot brackets, Andrews or Roth prescriptions, while the recently qualified orthodontists preferred the 0.022-inch slot and MBT prescription. Keim et al. (2014b) found that the routine use of Roth and Alexander prescriptions, as well as 0.018-inch slot brackets, were significantly increased with the number of years in orthodontic practice in the United States, whereas the MBT system and 0.022-inch slot brackets had generally shown the reverse trend.

3.2.8 Conclusions

This survey indicates that the vast majority of UK specialist orthodontists use conventional ligating MBT prescription brackets with the 0.022-inch slot size. This was mainly because they perceive this combination provides better treatment outcomes, whilst many respondents also indicated they were taught and trained using this combination and that there was no evidence to support or reject a change in their clinical practice.

CHAPTER 4: AIMS, OBJECTIVES, AND HYPOTHESES OF THE STUDY

4.1 AIM

The aim of the present study is to compare the effectiveness of orthodontic treatment with the 0.018-inch and 0.022-inch slot bracket systems.

4.2 OBJECTIVES

4.2.1 Primary Objective

To investigate any difference between the 0.018-inch and 0.022-inch slot conventional pre-adjusted MBT bracket systems in terms of orthodontic treatment duration.

4.2.2 Secondary Objectives

1. Quality of Treatment

To investigate any difference between the 0.018-inch and 0.022-inch slot conventional pre-adjusted MBT bracket systems in terms of:

- Orthodontic treatment outcomes using the ABO CR-EVAL and PAR indices.
- Amount of maxillary and mandibular incisor inclination/torque.
- Amount of maxillary first molar anchorage loss for bilateral premolar extraction cases.
- Patient experience with wearing fixed orthodontic appliances.
- Patient satisfaction with fixed appliance orthodontic treatment.

2. Biological Side Effects of Treatment

To investigate any difference between the 0.018-inch and 0.022-inch slot conventional pre-adjusted MBT bracket systems in terms of apical orthodontically-induced inflammatory root resorption of maxillary central incisors.

4.3 NULL HYPOTHESES

4.3.1 Hypothesis 1:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *time required to complete orthodontic treatment.*

4.3.2 Hypothesis 2:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *quality of orthodontic treatment outcome when measured using the ABO Cast-Radiograph Evaluation and PAR indices*.

4.3.3 Hypothesis 3:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *incisor inclination near end of orthodontic treatment.*

4.3.4 Hypothesis 4:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *first molar anchorage loss on completion of orthodontic treatment.*

4.3.5 Hypothesis 5:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *patient experience with fixed appliances during orthodontic treatment.*

4.3.6 Hypothesis 6:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *patient satisfaction with fixed appliance orthodontic treatment.*

4.3.7 Hypothesis 7:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *OIIRR after nine months of orthodontic treatment.*

CHAPTER 5: SUBJECTS AND METHODS

5.1 STUDY DESIGN

This study is a multicentre non-stratified prospective randomised clinical trial designed as a blinded (masked), parallel group trial with equal randomisation (1:1 allocation ratio) to evaluate which of the 0.018-inch or 0.022-inch slot pre-adjusted MBT bracket systems is more effective. The study was conducted in Scotland, United Kingdom. It was supported by the UK National Health Service (NHS) for NHS support costs. The University of Dundee provided academic sponsorship and 3M-Unitek provided brackets and wires. Ethical approval was obtained from the NHS Tayside Committee on Medical Research Ethics (East of Scotland Ethics Service) in October 2009 (REC Reference: 09/S1401/56). Research and Development (R&D) approval was obtained from the NHS Tayside Research and Development in November 2009. The trial was registered with ClinicalTrials.gov on 5th March 2014, registration number: NCT02080338.

5.2 STUDY SETTINGS

The study was conducted in NHS Tayside secondary care settings in Scotland, United Kingdom. Three centres were involved in patient recruitment for the study. These were:

- Dundee Dental Hospital and School
- Perth Royal Infirmary
- Springfield Medical Centre (Arbroath)

All these centres were hospital based consultant-led orthodontic units, treating NHS patients. Clinicians were either specialist orthodontists (on the GDC Specialist List) or in training to become specialist orthodontists.

5.3 PARTICIPANTS

Patients were invited to participate in the study from January 2010 to September 2014. The participants were selected according to the following criteria:

5.3.1 Inclusion Criteria

1. Patients aged 12 years and above.
2. Patients with any type of malocclusion who were scheduled for dual arch fixed appliance orthodontic treatment.

5.3.2 Exclusion Criteria

1. Patients who had undergone previous orthodontic treatment.
2. Patients with orofacial clefts, severe hypodontia, and patients with special needs.
3. Patients where orthodontic-orthognathic surgery treatment was required.

5.4 SAMPLE SIZE CALCULATION

The sample size calculation is based on the primary outcome of duration of orthodontic treatment. Using nQuery Advisor 7.0, the sample size was calculated to detect a difference of three months in the mean duration of orthodontic treatment, which was considered as a clinically significant difference. The standard deviation was estimated according to the studies by Amditis and Smith (2000) and Eberting et al. (2001). Therefore, a sample size of 92 patients in each group was expected to have 80% power to detect this difference assuming that the common standard deviation is 7.2 months using a two group t-test with a 0.05 two-sided significance level. Anticipating a dropout rate of 15% to 20%, the total number of participants planned to be recruited for this study was 216 (El-Angbawi et al., 2014).

5.5 PATIENT ALLOCATION AND INTERVENTIONS

5.5.1 Diagnosis and Patient Identification

Routine diagnostic procedures as a part of orthodontic treatment were undertaken for every patient prior to consent for the study:

1. ***Orthodontic diagnosis:*** this comprised an intra-oral and extra-oral assessment.
2. ***Study models:*** trimmed maxillary and mandibular dental stone study models were produced after taking alginate impressions and a wax bite to record maximum intercuspal position.
3. ***Photographs:*** intra-oral and extra-oral colour photographs were taken by a Medical Photographer.
4. ***Radiographs:*** these were taken as clinically indicated and included periapical, bitewing, occlusal, panoramic, and cephalometric radiographs as appropriate.

5.5.2 Information Sheet

Patients who met the inclusion criteria for the study received the patient information sheet and where relevant the parent information sheet was issued (Appendix 1). The nature of the study was explained by one of the clinical trial team. The information sheet was designed specifically for this trial in the form of a series of questions and answers that explained in lay terms all the information relating to the study for the participant/parent. The participants were asked to take the patient information sheet home to read the study process carefully and to provide their decision about participation at the following appointment which was at least two weeks after the first appointment. At the subsequent appointment, any enquires from the patient/parent were resolved by one of the research team to make sure that all the patients had sufficient information about the trial. An independent clinician (Dr. D. Evans), who was not part of the trial research group, agreed to be an independent reference for the

participants/parents in case there were any further queries regarding the study. Therefore, his contact information was included in the patient/parent information sheet.

5.5.3 Consent Process

The consent process was completed after obtaining patient/parent assent to participate in the study. This was undertaken by one of the five eligible research team clinicians who had been trained in Good Clinical Practice. The duty of the researcher was to make sure that the patient/parent had read and understood the information sheet thoroughly and then to complete the informed consent/assent form with the patient/parent (Appendix 2). Three copies of the completed consent/assent form were generated for each patient; one was given to the patient/parent, while the second and third copies were kept in the patient's casenotes and the trial site file.

Once each patient had consented to participate in the study, they were randomised to one of the study groups, i.e. either treatment with 0.018-inch slot brackets **(0.018'' group)** or with 0.022-inch slot brackets **(0.022'' group)**, using the MBT prescription (Victory series, 3M-Unitek, Monrovia, California). Any remaining initial records were also completed at this stage before starting treatment. Figure 6 illustrates the steps for patient identification and allocation during the initial appointments prior to the start of treatment.

5.5.4 Randomisation

5.5.4.1 Sequence Generation

In order to ensure an equivalent number of participants in each treatment group, a simple blocked randomisation without stratification was used. A computer random number generator was implemented to select random permuted blocks with a block size of ten and an equal allocation ratio (http://www.graphpad.com/quickcalcs/randomn2.cfm). Using this system, the odd

numbers were assigned to group 1 and the even numbers to group 2. The sequence was checked to make sure that even and odd numbers were equal in each ten number block in the random table. Then, each number in the random table was given a study number in order to create the final Allocation Table for the participants in the study (which contained the study number and allocation group). This table was kept in a sealed envelope away from the clinical environment.

5.5.4.2 Allocation Concealment

Allocation concealment was achieved with sequentially numbered, identical, opaque, and sealed envelopes which were prepared before the trial. Each envelope was given a study number and contained the treatment allocation card (group 1 or group 2). These envelopes were kept in a labelled box in a known place in the clinic. As the clinician obtained the informed consent form the patient/participant, an independent dental nurse was responsible for identifying the next allocation envelope in the sequence to implement the randomisation process. The allocation envelope was only opened at the time of appliance placement in front of the participant so that both the clinician and the participant were aware of the allocation group.

A List of Study Participants was then created and registered at each trial centre. This contained only the study number (which became the study ID number for each participant) and the unique hospital number (CHI number) but not the allocation group. A List of Patients who declined to Participate in the Study was also created and registered. Both of these lists were kept in the trial investigator site file.

5.5.5 Blinding/Masking

Due to the nature of this orthodontic trial, blinding to treatment allocation was only possible for the investigator and data analyst, while it was not possible for the clinicians and patients. As soon as the allocation envelope was opened in preparation for appliance placement, both clinician and participant knew the type of appliance used (0.018-inch or 0.022-inch slot brackets). This was recorded in the patient's casenotes in order to allow the clinicians to follow the recommended standard sequence of archwires for each appliance. Although patients were aware of the allocation group, they did not have previous experience with orthodontic treatment and could not recognise the difference between appliances.

All the trial documents were labelled with study ID number, which together with the unique hospital identification number and model box number were used for participant identification and data collection. It should be noted that none of these numbers revealed the allocation group. The only document that could unmask the allocation group was the Allocation Table which contained the study ID and relevant allocation group. This was kept locked away from the investigator and analyst until the completion of data collection and measurement.

5.5.6 Intervention Protocol

The treatment involved initially polishing the teeth with pumice and water, and using a self-etching primer (Transbond™ Plus Self Etching Primer, 3M-Unitek, Monrovia, USA) to prepare the teeth for bracket placement. Adhesive pre-coated (APC) brackets/buccal tubes (APC™ II Victory Series™ Twin MBT™, 3M-Unitek, Monrovia, USA) were bonded according to the allocation group, i.e. either 0.018-inch or 0.022-inch slot MBT prescription. Bands were used on molars where a transpalatal arch or quadhelix was required

A predetermined archwire sequence for each bracket slot system was followed:

0.018-inch slot bracket system

- 0.016-inch super elastic nickel-titanium archwire
- 0.016 × 0.022-inch super elastic nickel-titanium archwire
- 0.016 × 0.022-inch stainless steel archwire

0.022-inch slot bracket system

- 0.016-inch super elastic nickel-titanium archwire
- 0.019 × 0.025-inch super elastic nickel-titanium archwire
- 0.019 × 0.025-inch stainless steel archwire

Appliances were routinely adjusted at an interval of 6-8 weeks. All the participants received a standard treatment regime according to the treatment protocol throughout the trial so that the only difference between them was the type of bracket slot size and the relevant archwires. Minor deviations from the standard protocol were accepted for certain clinical circumstances (e.g. use of “piggy back” wires), but no special techniques or additional appointments were required for the study.

Periapical radiographs with a long cone paralleling technique for the maxillary central incisors were taken at the start of treatment and after nine months from the start of treatment. In addition, digital lateral cephalometric radiographs were taken at the start and near end of treatment [UK orthodontic radiography guidelines by Isaacson et al (2008), updated by Isaacson et al. (2015)]. Three questionnaires for patient perception were completed before, during and after treatment plus pre- and post-treatment IOTN AC.

5.5.7 Interim Analyses and Stopping Guidelines

Using the nine months periapical radiographs, should any concerns arise in relation to severe apical orthodontically-induced inflammatory root resorption of more than one

third of the root (score 3 or more) (Malmgren et al., 1982) being detected in the majority of patients in one group, whilst minor changes in the other group, this would mandate that the trial monitoring committee should be convened to consider whether the study would be terminated (El-Angbawi et al., 2014). This evaluation was undertaken by an independent clinician *Professor Helen Worthington* from the University of Manchester who was consulted to perform this assessment at the end of the first year in order to preserve masking regarding the study groups.

5.6 TRIAL MONITORING COMMITTEE

The trial monitoring committee was initially composed of three researchers; Professor David Bearn, Professor Grant McIntyre, and Dr. Ahmed El-Angbawi (during the first part of the trial). In the second part of the trial, it was composed of Professor David Bearn, Professor Grant McIntyre, and Dr. Yassir A. Yassir. The committee met regularly every two weeks to assess and discuss the progress of the trial and to ensure that the protocol was followed adequately.

5.7 DATA COLLECTION

A specially designed sheet was used to collect patient-related and treatment-related variables. These included data before, during, and after orthodontic treatment throughout the trial.

For each participant, all the trial documents, including information sheet, informed consent, questionnaires, IOTN, and the flowchart of the first and second appointments procedures (Figure 6) were kept in a folder attached with the patient's casenotes. Additionally, a unique trial label with study ID number and including a list of all the required data/records with their time of collection with tick boxes was placed on the front cover of the patient's casenotes to remind the clinicians to collect them.

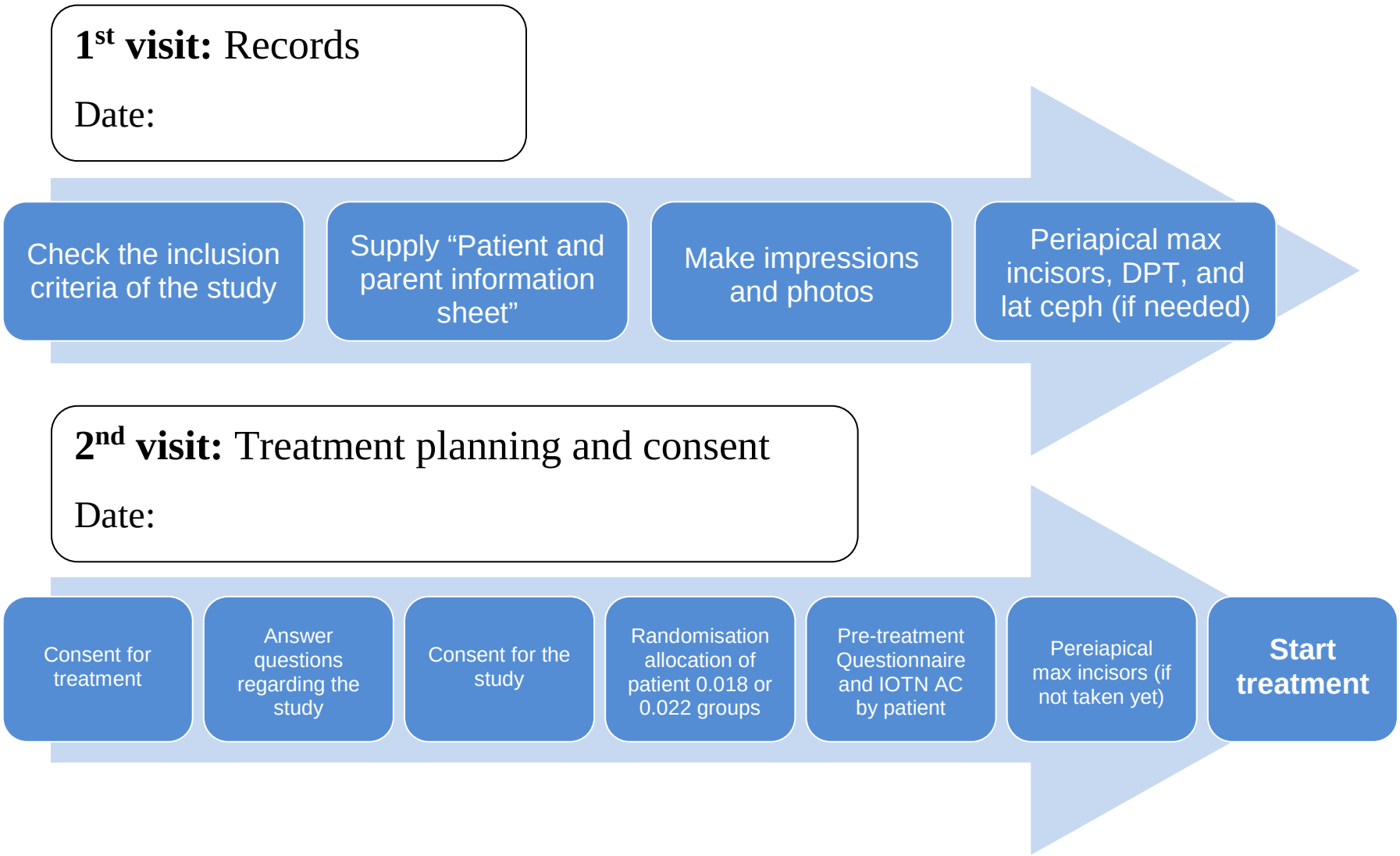

Figure 6: Flowchart for the first and second appointments for the patients participating in the study (El-Angbawi, 2013)

5.7.1 Summary of Records/Data Collected Throughout the Trial

- ***Treatment duration***, dates of main stages of treatment, number of appointments, unscheduled/emergency appointments, and cancelled/failed appointments, as well as different patient-related and treatment-related factors. These were recorded from patients' casenotes.
- ***Study models*** (orthodontically-trimmed) at the start and end of treatment.
- ***Photographs*** (colour, intra-oral and extra-oral) taken at the start and end of treatment.
- ***Radiographs****:*
  - Periapical radiographs with a long cone paralleling technique for the maxillary central incisors were taken at the start of treatment and after nine months from the start of treatment.
  - Digital true lateral cephalometric radiographs were taken at the start and near end of treatment in the finishing stage.
- ***Questionnaires and IOTN AC****:*
  - Pre-treatment Questionnaire and pre-treatment IOTN AC were completed at the start of treatment
  - Smiles-Better Questionnaire was completed after six months from the start of treatment
  - Post-treatment Questionnaire and post-treatment IOTN AC were completed at the end of treatment.

5.8 OUTCOME MEASURES

The following domains: *treatment duration*, *treatment quality*, and *biological side effects of treatment* were compared between the two appliance groups (0.018'' and 0.022'').

5.8.1 Primary Outcome

5.8.1.1 Duration of Treatment:

This included comparing the *overall orthodontic treatment duration* measured in months. The following measurements were also included:

- Comparing the time required to complete levelling and alignment stage.
- Comparing the time required to complete working and finishing stage.
- Comparing the number of visits required to complete orthodontic treatment.
- Factors influencing orthodontic treatment duration.

5.8.2 Secondary Outcomes

5.8.2.1 Quality of Treatment:

- Comparing the quality of orthodontic treatment outcome using the ABO CR-EVAL and PAR indices (study models).
- Comparing the amount of maxillary and mandibular incisor inclination/torque at the end of treatment (digital lateral cephalograms).
- Comparing the amount of maxillary first molar anchorage loss for bilateral premolar extraction cases (digital study models).
- Comparing patient experience with fixed appliances during orthodontic treatment using the Smiles-Better Questionnaire (Orthodontic Experience Questionnaire).

- Comparing patient expectations and satisfaction with orthodontic treatment using the Pre-treatment and Post-treatment Questionnaires.
- Comparing the improvement in dental attractiveness using the Aesthetic Component of the Index of Orthodontic Treatment Need (IOTN AC).

5.8.2.2 Biological Side Effects of Treatment

- Comparing the amount of apical orthodontically-induced inflammatory root resorption (OIIRR) measured from the nine months periapical radiographs for maxillary central incisors. This measurement was reported for the first part of this trial by El-Angbawi (2013). However, a completed measurement of the entire sample was undertaken in the current study.

The following section includes detailed methods of measurement for each outcome. Data collection and measurement were undertaken blindly by the principal investigator (Yassir A. Yassir), except for OIIRR (measured by David Bearn and Grant McIntyre) and the PAR scores (measured by a calibrated Orthodontic Technician).

5.9 DURATION OF TREATMENT

Treatment records were collected and data were recorded and analysed. The treatment duration was measured in months required to complete treatment. Greater than three months difference in active treatment duration between the two appliance types was regarded as being a clinically significant difference.

5.9.1 Data Collection

The data collection sheet was used to collect data for the overall orthodontic treatment duration from the patients' casenotes. This included data before, during, and after treatment.

The following dates were recorded: date of appliance bonding (D1); date of inserting rectangular stainless steel archwire (D2); and date of appliance debond (D3). The duration of orthodontic treatment was measured by the number of months required to complete treatment from D1 to D3, without regard to the use of any banded auxiliary appliance. The duration of the levelling and alignment stage (from D1 to D2) and the working and finishing stage (from D2 to D3) were also calculated in addition to the total number of appointments. Different patient-related and treatment-related factors were collected to identify if they influenced the duration of treatment (Table 51).

Table 51: Dependent and independent variables used to determine treatment duration and factors influencing it

Dependent Variables	
Main Outcome	Duration of overall treatment
	Duration of levelling and alignment stage
	Duration of working and finishing stage
Independent Variables	
Factors that might influence treatment duration	
Patient-Related Factors	
Demographic Factors	Age
	Gender
Patients Characteristics	Type of malocclusion
	Presence or absence of impacted teeth
	Severity of malocclusion (Pre-treatment PAR score)
Patient Cooperation	Number of failed appointments
	Number of emergency appointments
	Number of debonded brackets/“broken” appliance
Treatment-Related Factors	
Treatment Modality	Presence or absence of extracted teeth
	Presence or absence of anchorage device
	Presence or absence of intermaxillary elastics
	Type of bracket slot
	Was archwire sequence followed
	Number of clinicians (one or more than one)
Quality of Treatment	Degree of case improvement (% PAR reduction)
	Quality of treatment outcome (ABO CR-EVAL index)

5.10 QUALITY OF TREATMENT

5.10.1 Model Analysis (ABO CR-EVAL)

Study models with bubbles or broken teeth or those that were incorrectly trimmed were excluded. The guidelines for study model analysis were obtained from the instructions provided by the American Board of Orthodontics (Casko et al., 1998). This study only included the model analysis and excluded the panoramic radiographic analysis (root angulation component) because the trial did not involve post-treatment panoramic radiographs in accordance with the UK orthodontic radiography guidelines (Isaacson et al., 2008, updated by Isaacson et al., in 2015).

The components of the ABO CR-EVAL measured in this study are described with their rationale as follows (Casko et al., 1998):

Alignment: this is one of the primary objectives of orthodontic treatment and evaluation of alignment is important for the quality assessment of orthodontic treatment results.

Marginal ridges: these are measured to evaluate adequate vertical positioning of the posterior teeth.

Buccolingual inclination: this is measured to evaluate the buccolingual angulation of the posterior teeth.

Overjet: this is measured to evaluate the relative anteroposterior relationship of the anterior teeth and the transverse relationship of the posterior teeth.

Occlusal contacts: these are measured to evaluate the adequacy of the posterior occlusion.

Occlusal relationship: this is measured to evaluate the relative anteroposterior position of the maxillary and mandibular canines and posterior teeth.

Interproximal contacts: these are measured to determine if all the dental arch spaces have been closed.

Post-treatment study models were measured according to the above seven criteria and scored as 0, 1, or 2 depending on the amount of deviation from the standards established by the ABO (Table 52). The overall score of the ABO CR-EVAL for each treated case represents the sum of points lost of these criteria. The three categories of the total ABO CR-EVAL score were identified (Casko et al., 1998). Cases with a total score loss of less than 20 points (satisfactory or passed), cases with a total score of 20-30 points (undetermined), and cases with a total score of more than 30 points (not passed or incomplete).

Table 52: The ABO CR-EVAL (Casko et al., 1998; Schabel et al., 2008)

Component	Deduction	Component	Deduction
Alignment/Rotations		**Occlusal relationships**	
< 0.5 mm	0	< 1 mm	0
0.5 to 1 mm	1	1 to 2 mm	1
> 1 mm	2	> 2 mm	2
Marginal ridge height		**Overjet**	
< 0.5 mm	0	0 mm	0
0.5 to 1 mm	1	Less than 1 mm	1
> 1 mm	2	> 1 mm	2
Buccolingual inclination		**Interproximal contacts**	
< 1 mm	0	< 0.5 mm	0
1 to 2 mm	1	0.5 to 1 mm	1
> 2 mm	2	> 1 mm	2
Occlusal contacts		**ABO Categories**	
0 mm	0	Passed	< 20
< 1 mm	1	Undetermined	20-30
> 1 mm	2	Not passed	> 30

5.10.1.1 Reproducibility of the Measurements

The principal investigator was calibrated in the use of the ABO CR-EVAL measurement with the aid of the ABO CR-EVAL calibration kit (written manual with scoring sheets, three sets of dental casts, and the ABO measuring gauge) with the instructions obtained from a demonstration video describing the guidelines for the measurements by the former head of the ABO. The video is available on the ABO website: https://www.americanboardortho.com/orthodontic-professionals/about-board certification/downloads-and-references/measurement-demonstration/. More information about the measurement was also obtained after direct correspondence with the ABO in the United States of America. Training using the calibration kit was repeated several times on different occasions until the investigator's results were comparable with that on the scoring sheet provided by the ABO.

Figure 7: The ABO measurement gauge (Casko et al., 1998)

5.10.2 Model Analysis (PAR)

The Peer Assessment Rating (PAR index with the British weightings) was used to measure the severity of malocclusion for 143 patients on their study models before treatment and to identify the degree of improvement after treatment (Richmond et al., 1992a). The scoring was performed by an Orthodontic Technician who was calibrated with PAR measurement and was also masked to study group allocations. This was undertaken as part of the routine NHS Tayside evaluation for cases treated in the trial centres.

5.10.3 Incisor Inclination

Lateral cephalometric radiographs were collected from the trial centres. Each case included pre-treatment and near end of treatment digital cephalometric radiographs.

The inclination of the maxillary and mandibular incisors were measured by calculating the angle between the long axis of the maxillary central incisors and the maxillary/palatal plane (anterior nasal spine – posterior nasal spine) and the angle between the long axis of mandibular central incisors and the mandibular plane (Gonion – Menton). Every lateral cephalometric radiograph was digitised using the AutoCAD® 2007 (www.autodesk.co.uk) software program to calculate the angular measurements. First of all the cephalometric points were located before lines were constructed to join these points to form cephalometric angles. The angles were measured directly as they were not affected by magnification.

5.10.3.1 Cephalometric Points

1. ***Point ANS (Anterior Nasal Spine):*** the tip of the bony anterior nasal spine in the median plane (Rakosi, 1982).
2. ***Point PNS (Posterior Nasal Spine):*** this is a constructed radiological point, the intersection of a continuation of the anterior wall of the pterygopalatine fossa and the floor of the nose. It marks the dorsal limit of the maxilla (Rakosi, 1982).
3. ***Point Is (Incisor superius):*** the tip of the crown of the most anterior maxillary central incisor (Rakosi, 1982).
4. ***Point Ii (Incisor inferius):*** the tip of the crown of the most anterior mandibular central incisor (Rakosi, 1982).
5. ***Point Ap 1 (Apicale 1):*** the root apex of the most anterior maxillary central incisor (Rakosi, 1982).

6. ***Point Ap $\overline{1}$ (Apicale $\overline{1}$):*** the root apex of the most anterior mandibular central incisor (Rakosi, 1982).
7. ***Point Me (Menton):*** the lowest point on the symphyseal shadow of the mandible seen on a lateral cephalogram (Caufield, 1995).
8. ***Point Go (Gonion):*** a point on the curvature of the angle of the mandible located by bisecting the angle formed by the lines tangent to the posterior ramus and inferior border of the mandible (Caufield, 1995).

5.10.3.2 Cephalometric Planes

1. ***Palatal plane (PP):*** the plane joining the anterior nasal spine and posterior nasal spine (Rakosi, 1982).
2. ***Mandibular plane (MP):*** formed by the line joining Gonion and Menton (Rakosi, 1982).

5.10.3.3 Cephalometric Measurements

1. ***Maxillary incisor-palatal plane angle (U1-PP):*** the angle between the long axis of the most anterior maxillary central incisor and the palatal plane, posteriorly (Rakosi, 1982) (Figure 8).
2. ***Mandibular incisor-mandibular plane angle (L1-MP):*** the angle between the long axis of the most anterior mandibular central incisor and the mandibular plane, posteriorly (Downs, 1948; Riedel, 1952) (Figure 8).

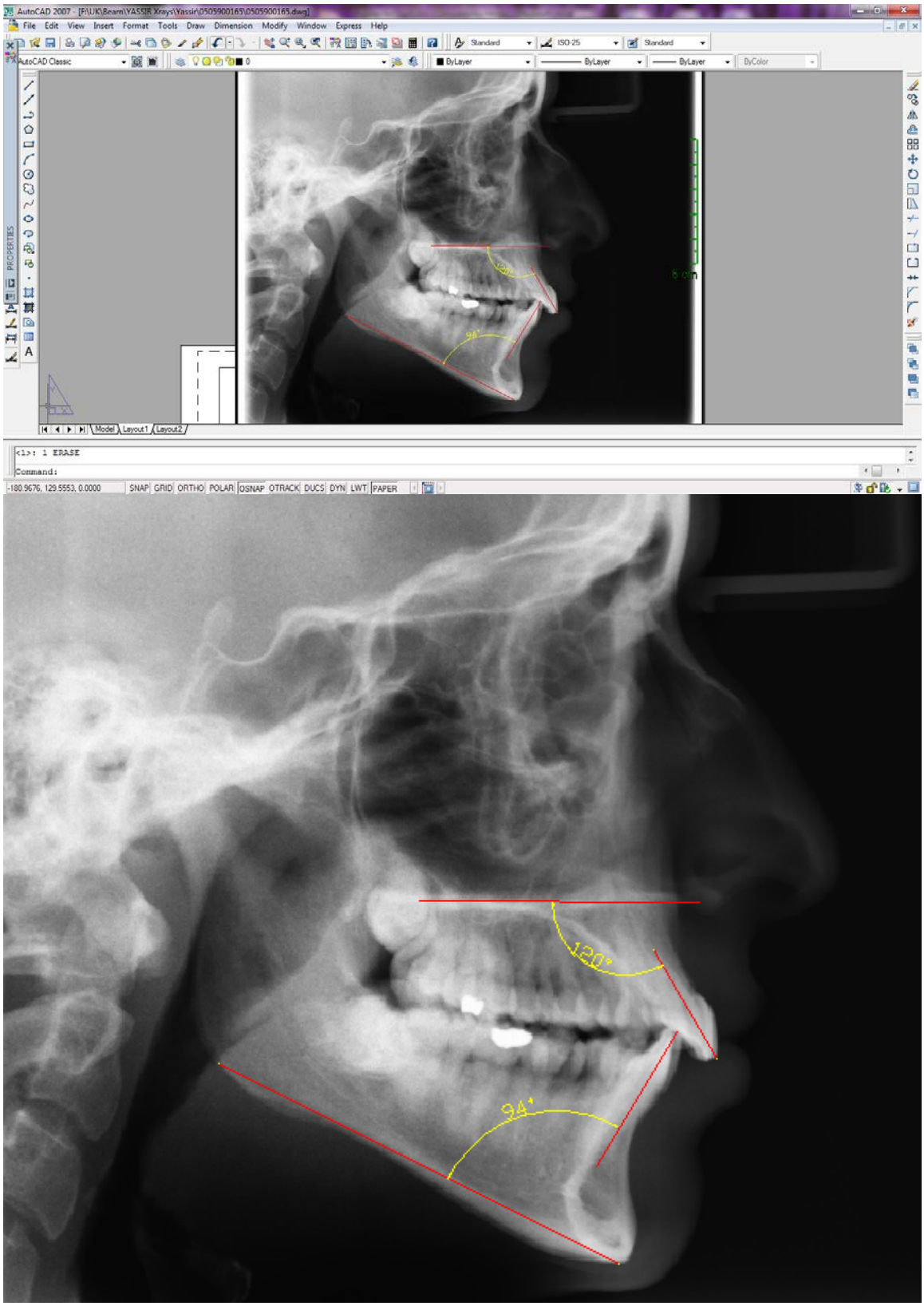

Figure 8: AutoCAD® software. U1-PP and L1-MP angles

5.10.4 Anchorage Loss

The sample included all the orthodontic patients with bilateral premolar extractions from the cohort of the current RCT. The cases were collected from the Orthodontic Clinics at the trial centres. Subjects were excluded if they had unilateral extractions or extraction of teeth other than premolars (e.g. first molars), hypodontia or defects such as bubbles or broken teeth on the study models.

Three-dimensional digital dental models were obtained pre- and post-treatment using a digital model scanner (R700, 3Shape, Copenhagen, Denmark) and OrthoAnalyzer software (3Shape, Copenhagen, Denmark) was used to identify the landmarks and calculate the measurements. The anteroposterior molar positional change was evaluated according to the method described by Ziegler and Ingervall (1989) and used by other studies (Rajcich and Sadowsky, 1997; Geron et al., 2003; Rajesh et al., 2014). The following landmarks were identified:

1. ***Anterior Raphe Point:*** the most detectable anterior point of the midpalatal raphe.
2. ***Posterior Raphe Point:*** the most detectable posterior point of the midpalatal raphe.
3. ***Right Rugae Point:*** the most medial point of the right third rugae.
4. ***Left Rugae Point:*** the most medial point of the left third rugae.
5. ***Right Molar Mesial Point:*** the mesial contact point of the right first permanent molar.
6. ***Left Molar Mesial Point:*** the mesial contact point of the left first permanent molar.

In order to calculate the linear measurement of molar positional change, a horizontal plane using the occlusal plane of the maxillary first molars was made using the OrthoAnalyzer software. The midpalatal raphe was identified as a median reference line, from the anterior to posterior raphe points. To determine the anteroposterior position of the first molars, a perpendicular line was projected from the mesial contact

point of the first molar to the median reference line bilaterally. Then the distance from this line to the third medial ruga point was measured in millimetres (Figure 9). Anchorage loss (AL) represents the value of subtracting post-treatment distance from the pre-treatment distance for both the right (ALR) and the left (ALL) sides. These values were then compared between the 0.018'' and 0.022'' groups to determine which system is superior regarding anchorage loss resistance. The investigator (Y.A.Y.) was trained and calibrated for using the OrthoAnalyzer software by both the manufacturer and a laboratory technician experienced in the use of digital models.

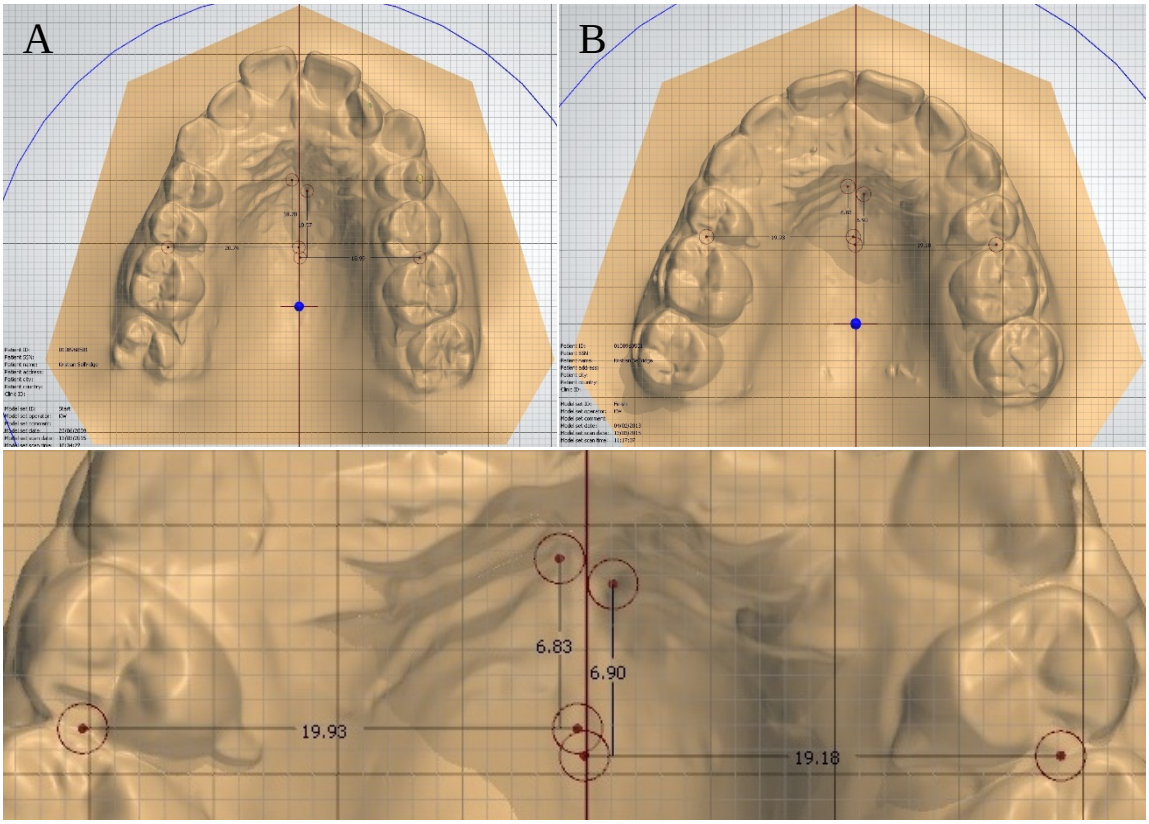

Figure 9: Anteroposterior first permanent molar distance to the medial end of the third palatal rugae (OrthoAnalyzer software). **A:** Pre-treatment, **B:** Post-treatment

5.10.5 Patient Perception of Fixed Appliance Orthodontic Treatment

The Pre-treatment, Smiles-Better, and Post-treatment Questionnaires were completed by the participants before treatment, after six months from the start of treatment, and after treatment, respectively.

These questionnaires were validated in this thesis using face and content validation (see Chapter 3, section 3.1). According to the results of validation, new shortened versions were produced and only the responses for the validated questions were analysed in this study. Data from these validated questionnaires were entered into a spreadsheet (Excel, Microsoft, Washington, USA) and then exported to SPSS software version 22.0 (SPSS Inc., Chicago, Illinois, USA) for analysis.

The Pre-treatment Questionnaire is related to patient expectations with fixed appliance orthodontic treatment and was completed by patients before commencing treatment. It contains items related to dental and facial appearance, self-concept and interpersonal relations, and oral function. It was rated using a 4-point Likert scale from “not a reason” to “very much a reason”. The Post-treatment Questionnaire is related to the impact of fixed appliance orthodontic treatment and patient satisfaction with treatment and was completed at the end of treatment. It contains items within the same domains of the Pre-treatment Questionnaire and they were rated as “no better”, “a little better”, “much better”, and “very much better” (Appendix 3, 5, 15, and 17).

Participants were asked to complete the Smiles-Better Questionnaire, about their experience with fixed appliances orthodontic treatment and its impact on their life, after six months from the start of treatment during one of their routine appliance adjustment appointments. The questionnaire was previously used by a research group at the University of Manchester to compare the effectiveness of two functional appliances

(O'Brien et al., 2003). It was validated in this thesis to be used for patients being treated with fixed orthodontic appliances. The items in the validated version of the Smiles-Better, which was later renamed the "Orthodontic Experience Questionnaire", were analysed in this study. The following domains were measured from the questionnaire (Appendix 4 and 16):

1. **Experience of wearing a brace:** this section includes the expectations of wearing a brace, extra appointments due to breakages and if this adversely affects the patient, cleaning the teeth and appliances, perception of tooth movement, and overall experience of treatment.
2. **Self-concept and interpersonal relations:** this section includes appearance, embarrassment, and teasing.
3. **Pain and function:** this section includes eating, sore teeth, soreness in the mouth, and soreness from rubbing
4. **Hobbies:** this includes the effects of wearing a brace on hobbies and interests.

Items were analysed using a 3-point Likert scale. The last open-ended question in the questionnaire is related to the overall experience of participants and was ranked by the study investigator into a positive comment, negative comment, or neutral.

5.10.5.1 IOTN AC

The Index of Orthodontic Treatment Need – Aesthetic Component (IOTN AC) (Brook and Shaw, 1989) is routinely used in orthodontic clinics for self-rating of dental attractiveness against a validated scale, before and after orthodontic treatment. The index is in the form of standardised series of ten intra-oral coloured photographs of teeth in occlusion. The participants were asked to identify the photograph that most resembled their own dental attractiveness, from 1 (most attractive) to 10 (least attractive) (Figure 10).

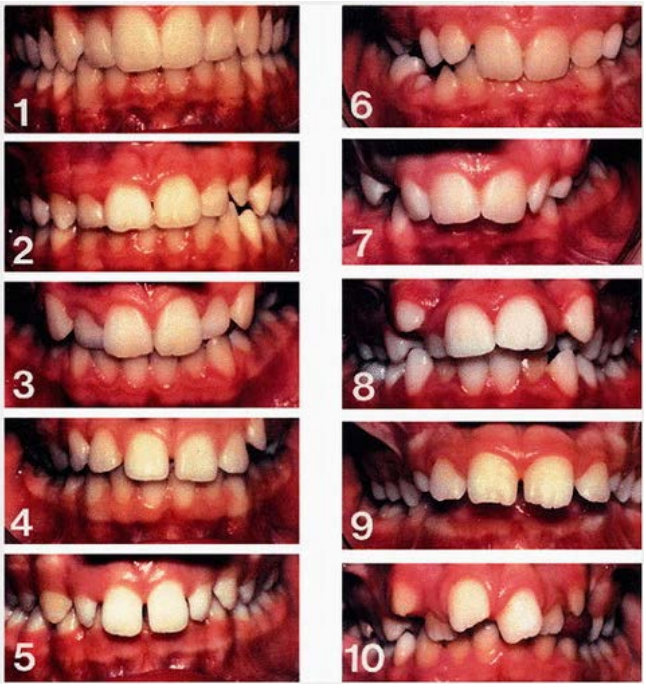

Figure 10: The aesthetic component of IOTN (©Victoria University of Manchester)

5.11 BIOLOGICAL SIDE EFFECTS OF TREATMENT

Apical OIIRR was measured in this study by assessing the severity of apical root resorption affecting the maxillary central incisors using long cone periapical radiographs. Periapical radiographs were taken for all trial participants before the start of treatment (T0) and at nine months after the start of treatment (T1). In order to ensure standardisation of the radiographs, radiographic film or digital sensor was placed using a film holder with a 40 cm film-source distance. The radiographs were generated at 60 kv and 7 mA Dc, 0.20 second.

The periapical radiographs, taken in this study, were of two types depending on availability in the study centres:

- **Digitised conventional film:** conventional film radiographs [F speed film (www.carestream.com)] were digitised using a flatbed scanner [Epson perfection v750PRO (www.epson.com)] as 16 bit grayscale images at 300 dpi.
- **Digital radiographs:** taken using the phosphor plate radiograph [Dürr Dental (www.duerr.co.uk)].

The first part of this trial confirmed the validity and high level of agreement of measuring root shortening from digital periapical radiographs produced by scanning conventional films when compared to the phosphor plate digital imaging (El-Angbawi et al., 2012; El-Angbawi, 2013).

All digital images were stored in a password protected computer located in the orthodontic department. The images were saved as JPG form and imported for measurements into Image J Link 1.4 software (https://imagej.nih.gov/ij/).

5.11.1 Method of Assessing Apical OIIRR from Periapical Radiograph

The severity of OIIRR was evaluated according to the scoring index that was provided by Malmgren et al. (1982) and Levander and Malmgren (1988) and illustrated in Figure 11.

- ***Grade 0:*** absence of apical root resorption.
- ***Grade 1:*** irregular apical root contour.
- ***Grade 2:*** minor apical root resorption, a small area of root loss amounting to less than 2 mm.
- ***Grade 3:*** severe apical root resorption from 2 mm to one third of the original root length.
- ***Grade 4:*** extreme apical root resorption exceeding one third of the original root length.

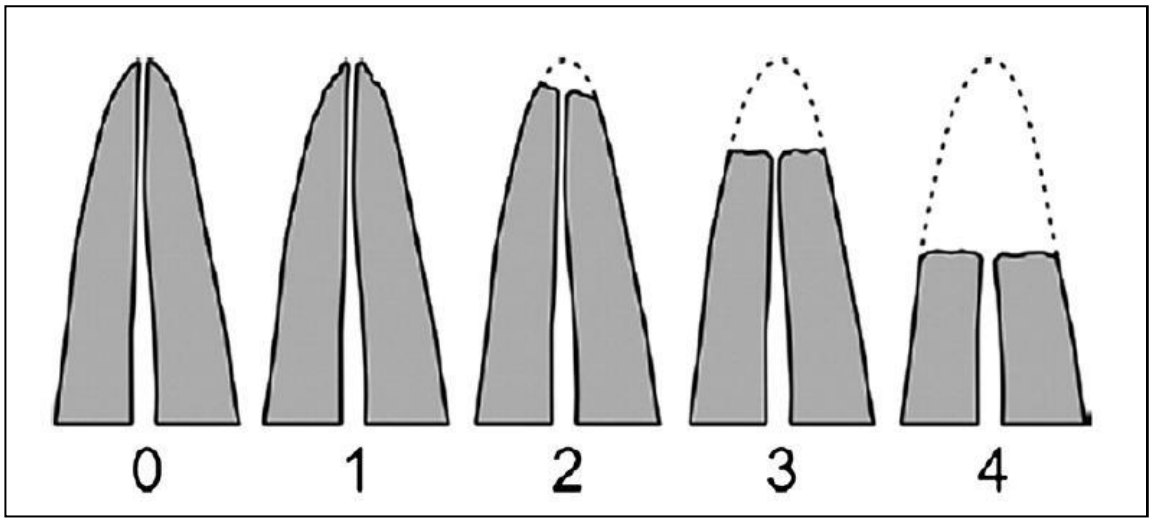

Figure 11: Scoring index for apical OIIRR (Malmgren et al., 1982). **0:** absence of apical root resorption. **1:** irregular root contour. **2:** minor apical root resorption (< 2 mm). **3:** severe apical root resorption (2 mm-⅓ of original root length). **4:** extreme apical root resorption (> ⅓ of original root length)

5.11.2 Method of Assessing Pre-Treatment Root Morphology

The pre-treatment periapical radiograph was used to evaluate root morphology for abnormality according to the index provided by Levander and Malmgren (1988) and illustrated in Figure 12.

- ***Score 0:*** normal root morphology.
- ***Score 1:*** short root.
- ***Score 2:*** blunt root.
- ***Score 3:*** root with apical bend.
- ***Score 4:*** root with apical pipette shape.

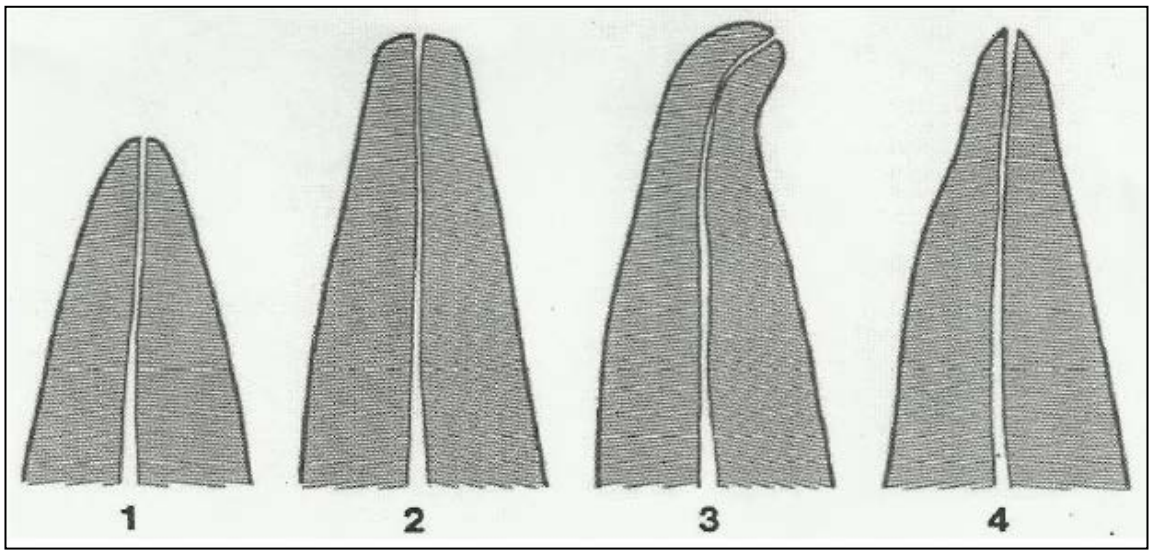

Figure 12: Scoring index for abnormal root morphology (Levander and Malmgren, 1988). **1:** short root. **2:** blunt root. **3:** root with apical bend. **4:** root with apical pipette shape

5.12 STATISTICAL ANALYSES

The data were analysed using the Statistical Package for Social Sciences for Windows, version 22.0 (SPSS Inc., Chicago, Illinois, USA). The following statistical analyses were used:

5.12.1 Descriptive Statistics

Descriptive statistics for dependent and independent variables were presented for each outcome according to appliance group. This included: number, mean, median, standard deviation, frequency, and percentage.

5.12.2 Reliability Statistics

- *ABO CR-EVAL:* an intraclass correlation coefficient (ICC) was used to test intra-examiner reliability of 20 study models measured twice with more than four weeks interval. Inter-examiner reliability was accomplished with the ABO calibration kit.
- *Incisor inclination:* the ICC was used to test intra-examiner reliability of 25 cephalometric radiographs measured twice with a four weeks interval.
- *Anchorage loss:* the ICC was used to test inter-examiner and intra-examiner reliability of 25 study models measured twice with a four weeks interval. A calibrated Orthodontic Technician participated in the inter-examiner reliability.
- *Root resorption:* weighted kappa test was used to test inter-examiner and intra-examiner reliability of 20 periapical radiographs scored twice with a four weeks interval.

5.12.3 Inferential Statistics

5.12.3.1 Two Group Comparisons

Levene's test was used to compare the variation between groups. Tests used to compare between the two appliance groups were: independent samples t-test and two-way ANOVA for continuous data, whilst a Chi-square, Mann-Whitney U test, and Related-samples Wilcoxon signed-rank test were used for categorical data. The significance level was set as $p < 0.05$ except where a Bonferroni correction was applied to control type I error. A 95% confidence interval was estimated for the mean difference between the study groups.

Note: *Results are presented as mean ± SD*

5.12.3.2 Regression Analysis

A multiple linear regression analysis was performed for the total study sample to identify factors influencing the duration of orthodontic treatment.

Inferential statistics used in this study are summerised in Table 53.

Table 53: Inferential statistics used in the study

Outcome measure	Type of Variables	Statistical Test
Comparing the overall orthodontic treatment duration between the two slot size groups	Continuous, assuming normal distribution	Independent samples t-test
Comparing the time required to complete levelling and alignment stage between the two slot size groups	Continuous, assuming normal distribution	Independent samples t-test
Comparing the time required to complete working and finishing stage between the two slot size groups	Continuous, assuming normal distribution	Independent samples t-test
Comparing the number of appointments required to complete treatment between the two slot size groups	Continuous, assuming normal distribution	Independent samples t-test
Identifying the factors influencing duration of orthodontic treatment for the total sample	Continuous, assuming normal distribution	Multiple linear regression analysis
Comparing the quality of orthodontic treatment outcome (PAR index) between the two slot size groups	Continuous, assuming normal distribution	Independent samples t-test
Comparing the individual components of the ABO CR-EVAL scores and the overall ABO CR-EVAL between the two slot size groups	Continuous and categorical data	Independent samples t-test and Mann-Whitney U test
Comparing the percentages of cases within each category of the ABO CR-EVAL between the two slot size groups	Categorical data	Chi-square test
Comparing the incisor inclination angle between pre-treatment and near end of treatment as well as between the two slot size groups	Continuous, assuming normal distribution	Two-way ANOVA
Comparing the anchorage loss between the right and left sides and between the two slot size groups	Continuous, assuming normal distribution	Two-way ANOVA
Comparing patient perceptions of orthodontic treatment between the two slot size groups	Categorical data	Chi-square test
Comparing IOTN between pre-treatment and post-treatment and between the two slot size groups	Categorical data	Wilcoxon signed-rank test and Mann-Whitney U test
Comparing OIIRR between T0 and T1 and between the two slot size groups	Categorical data	Wilcoxon signed-rank test and Mann-Whitney U test

CHAPTER 6: RESULTS

6.1 BASELINE DESCRIPTIVE DATA OF THE STUDY PARTICIPANTS

6.1.1 Subjects Participation and Dropouts

During the recruitment stage 216 patients were invited to participate in the study, however, 19 patients declined and 197 participants were enrolled in the study. Those were divided between the University of Dundee (166 patients) and Perth Royal Infirmary (31 patients) as the Springfield Medical centre was excluded from the study due to the inability to recruit patients for the study. Ten patients did not attend for appliance placement or declined to participate. Therefore, 187 patients were randomised to either the 0.018'' or 0.022'' group in a 1:1 ratio. Thirty-four participants were not included in the analysis. Of those, 20 participants were excluded or lost during the allocation and follow-up stages due to various reasons, while 14 participants were excluded during the analysis stage due to very poor compliance or protocol deviation. The total number of analysed participants was 153, with 77 participants in the 0.018-inch slot bracket group and 76 participants in the 0.022-inch slot bracket group. The CONSORT flowchart of the participants throughout the trial is shown in Figure 13. Patient recruitment started in January 2010 and ended in September 2014 and the trial was completed as planned.

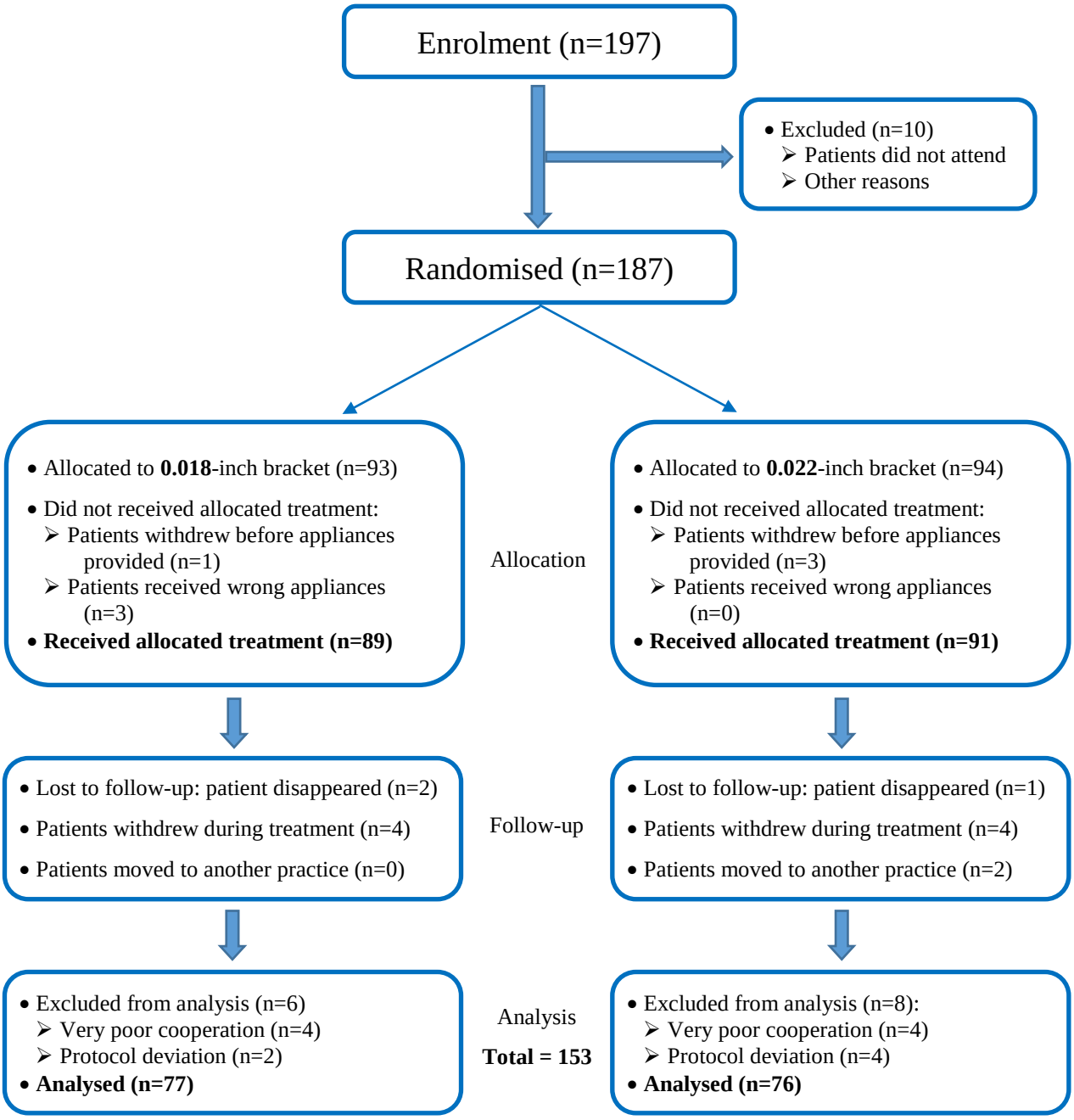

Figure 13: CONSORT flowchart of participants through each stage of the trial

6.1.2 Missing Data

Table 54 shows the percentage of missing data in different categories from the total analysed sample (153 participants).

Table 54: Missing data from the total analysed sample (N = 153)

Source of Data Collection	Missing in 0.018'' Group	Missing in 0.022'' Group	Total Missing	Total Retained	% of Missing
Patients' Casenotes	0	0	0	153	0.0%
Pre-treatment Study model	4	6	10	143	6.5%
Post-treatment Study model	4	4	8	145	5.2%
Pre-treatment Questionnaire	0	0	0	153	0.0%
Smiles-Better Questionnaire	0	0	0	153	0.0%
Post-treatment Questionnaire	6	5	11	142	7.2%
Pre-treatment IOTN	0	0	0	153	0.0%
Post-treatment IOTN	7	5	12	141	7.8%
Cephalometric Radiograph	17	8	25	128	16.3%
Periapical Radiograph	1	0	1	152	0.7%

6.1.3 Descriptive Statistics for Baseline Variables

6.1.3.1 Age

The descriptive statistics for age (years) of the participants at bonding in each group and for the total sample are shown in Table 55 and Figure 14.

Table 55: Descriptive statistics for age (years) of the participants at bonding

Group	N	Minimum	Maximum	Mean	SD
0.018’’	77	12.05	45.35	19.41	8.58
0.022’’	76	12.05	58.46	18.67	8.48
Total	153	12.05	58.46	19.05	8.51

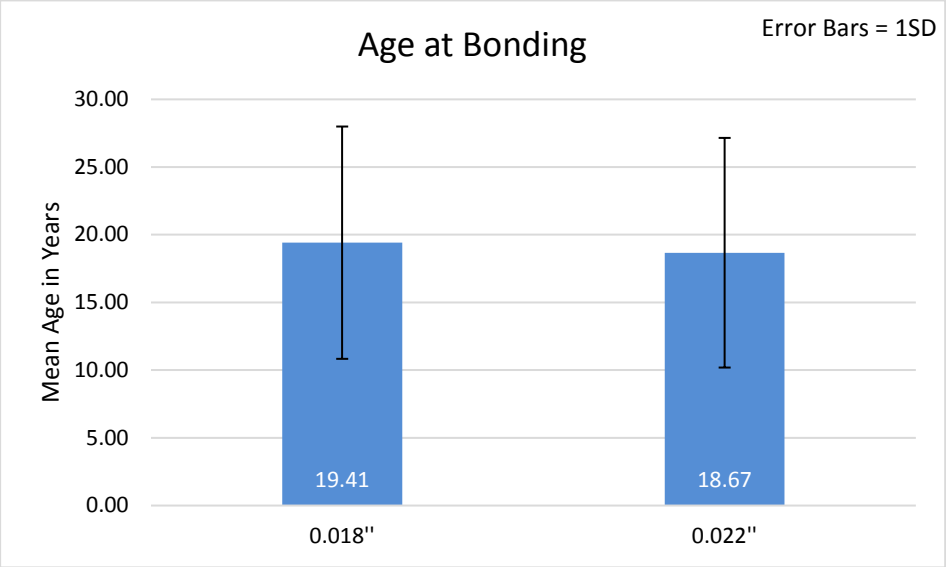

Figure 14: Mean age (years) of the participants at bonding in each group

6.1.3.2 Gender

The distribution of gender of the participants in each group and for the total sample is shown in Table 56 and Figure 15.

Table 56: Distribution of gender of the participants

Group	Female	%	Male	%	Total
0.018’’	56	72.7%	21	27.3%	77
0.022’’	49	64.5%	27	35.5%	76
Total	105	68.6%	48	31.4%	153

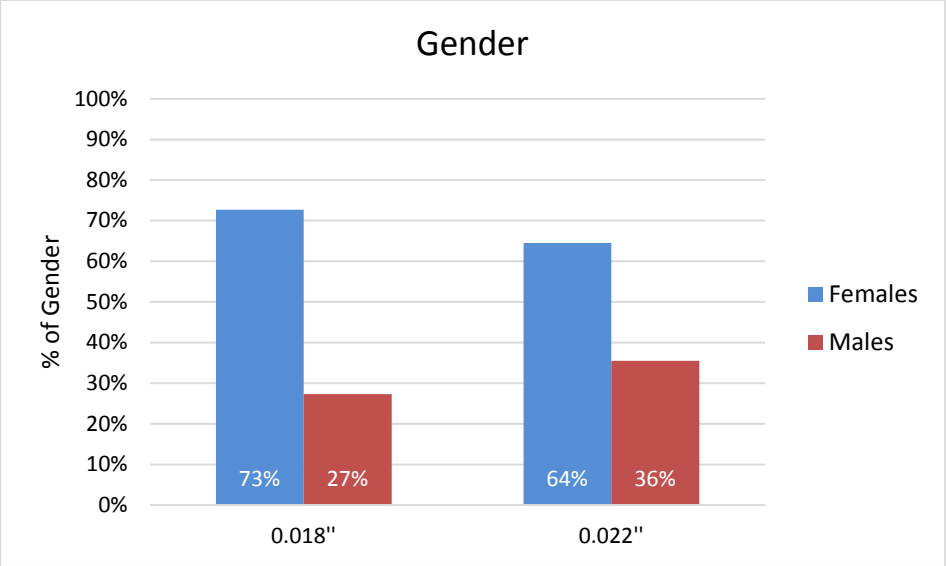

Figure 15: Distribution (%) of gender of the participants in each group

6.1.3.3 Type of Malocclusion

The distribution of types of malocclusion, using the British Standard Institute Classification for Incisor Relationships, in each group and for the total sample is shown in Table 57 and Figure 16.

Table 57: Distribution of types of malocclusion (British Standards Institute)

Group	Class I	%	Class II Div 1	%	Class II Div 2	%	Class III	%	Total
0.018’’	28	36.3%	19	24.7%	21	27.3%	9	11.7%	77
0.022’’	31	40.8%	23	30.2%	11	14.5%	11	14.5%	76
Total	59	38.6%	42	27.4%	32	20.9%	20	13.1%	153

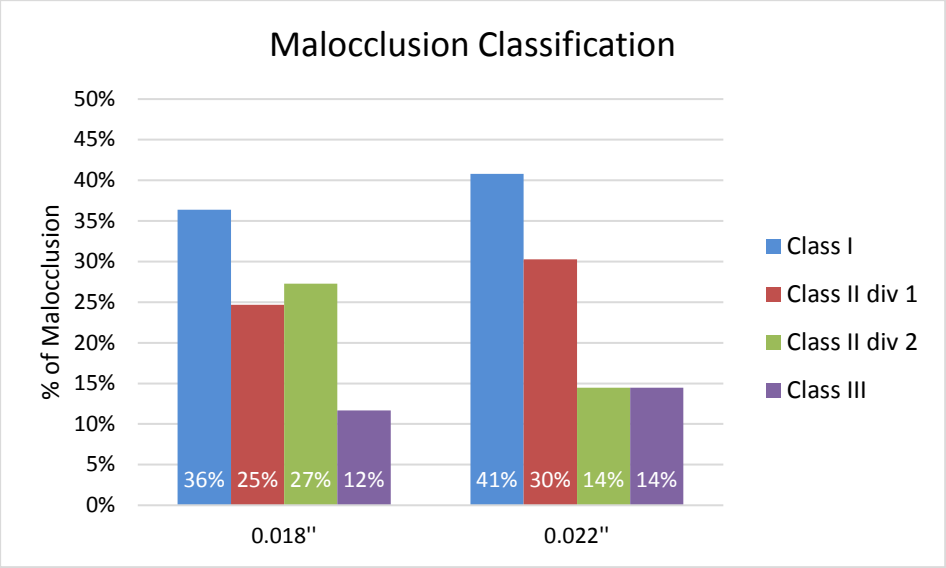

Figure 16: Distribution (%) of types of malocclusion in each group

6.1.3.4 Severity of Malocclusion

The descriptive statistics for the severity of the pre-treatment malocclusion, using the PAR scoring index, in each group and for the total sample are shown in Table 58 and Figure 17.

Table 58: Descriptive statistics for the pre-treatment PAR score

Group	N	Minimum	Maximum	Mean	SD
0.018’’	73	11	61	31.22	10.77
0.022’’	70	9	68	31.56	13.73
Total	143	9	68	31.38	12.27

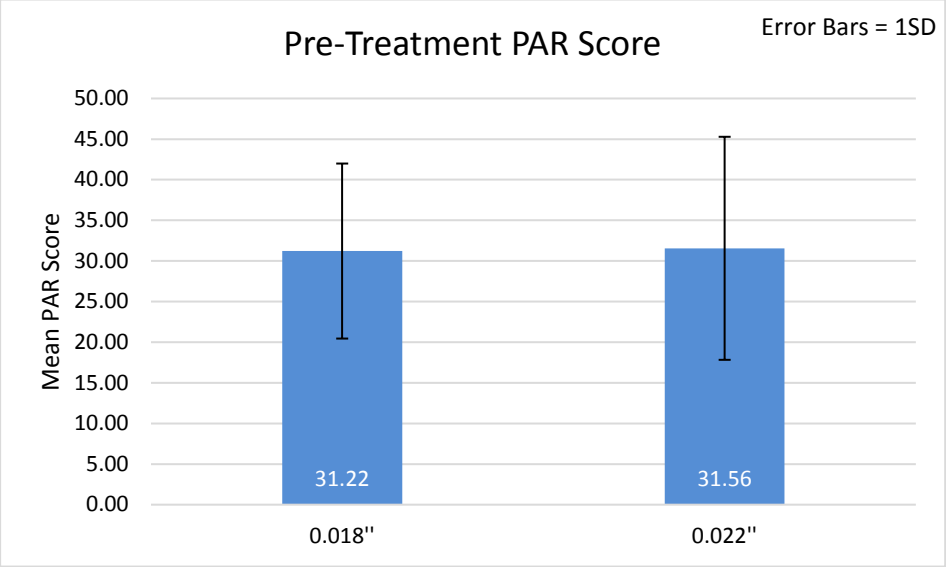

Figure 17: Mean pre-treatment PAR score in each group

6.1.3.5 Extracted and Impacted Teeth

The distribution of presence and absence of extracted and impacted teeth in each group and for the total sample is shown in Table 59 and Figures 18 and 19.

Table 59: Distribution of extracted and impacted teeth

Category	Group	No	%	Yes	%	Total
Extracted Teeth	**0.018’’**	18	23.4%	59	76.6%	77
	0.022’’	23	30.3%	53	69.7%	76
	Total	41	26.8%	112	73.2%	153
Impacted Teeth	**0.018''**	73	94.8%	4	5.2%	77
	0.022''	69	90.8%	7	9.2%	76
	Total	142	92.8%	11	7.2%	153

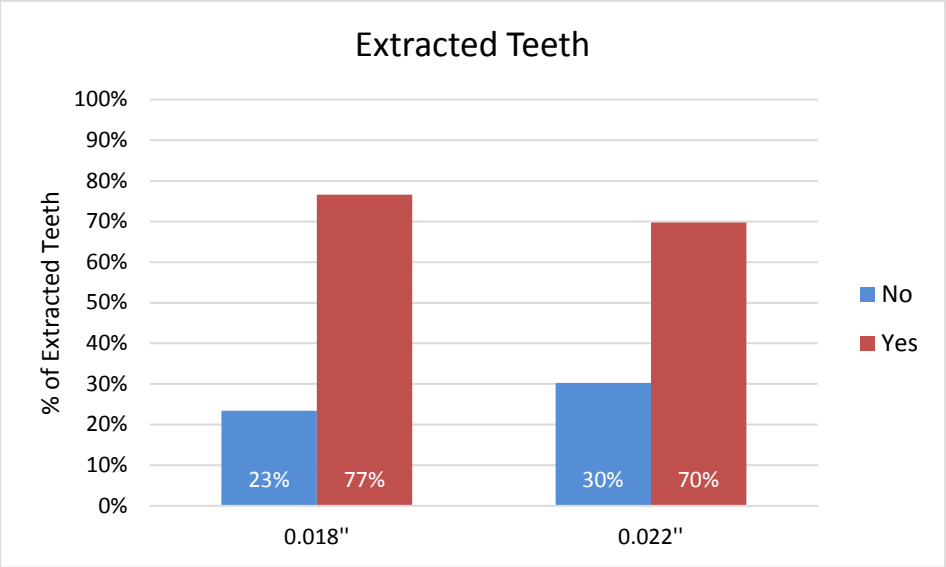

Figure 18: Distribution (%) of extracted teeth in each group

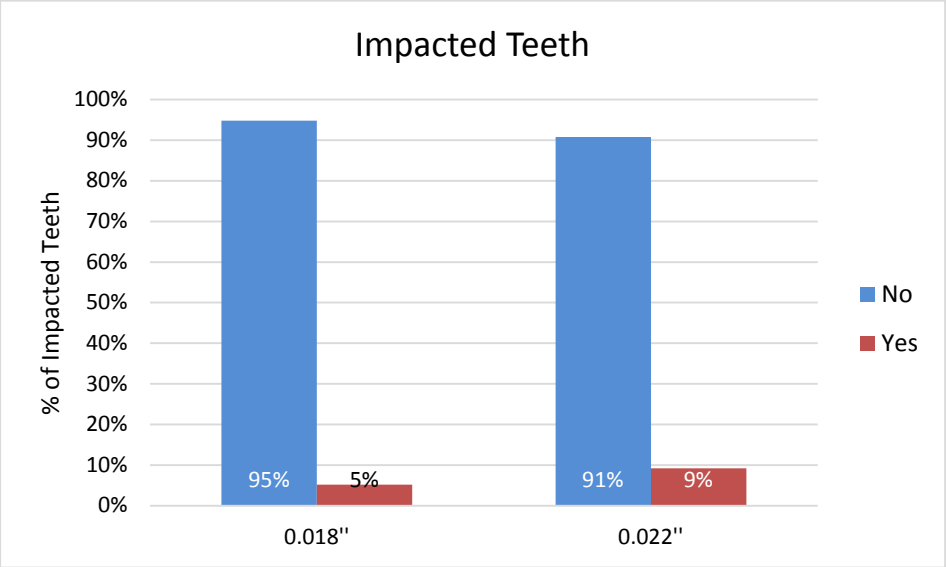

Figure 19: Distribution (%) of impacted teeth in each group

6.1.4 Comparison of Baseline Variables

In order to ensure that there was no significant difference between the baseline data for the appliance groups, the age, gender, type of malocclusion, severity of malocclusion, and number of extracted and impacted teeth were compared between the 0.018'' and 0.022'' groups using an independent samples t-test for continuous variables, while Chi-square with Fisher's exact tests were used for categorical variables. Table 60 shows that no statistically significant differences were found for these variables between the two groups.

Table 60: Comparison of the baseline variables between the groups

Continuous Variables	**t**	**df**	**p**
Age at Bonding	0.538	151	0.591
Pre-treatment PAR	-0.163	130.826	0.871
Categorical Variables	**Pearson Chi-Square**	**df**	**p (Fisher's Exact Test)**
Gender	1.210	1	0.299
Type of Malocclusion	3.852	3	0.281
Extracted Teeth	0.925	1	0.366
Impacted Teeth	0.924	1	0.368

*Significance level < 0.05

6.2 DURATION OF TREATMENT

6.2.1 Descriptive Statistics

6.2.1.1 Failed, Emergency Appointments, and Broken Appliances

The descriptive statistics for the number of failed and emergency appointments, as well as broken appliances (brackets, bands, and tubes) in each group and for the total sample, are shown in Table 61.

Table 61: Descriptive statistics for the number of failed, emergency appointments, and broken appliances

Category	Group	N	Minimum	Maximum	Median
Failed Appointments	**0.018''**	77	0	16	1
	0.022''	76	0	16	1
	Total	153	0	16	1
Emergency Appointments	**0.018''**	77	0	8	1
	0.022''	76	0	12	2
	Total	153	0	12	1
Broken Appliances	**0.018''**	77	0	20	2
	0.022''	76	0	14	3
	Total	153	0	20	2

6.2.1.2 Appointment Interval

The descriptive statistics for the appointment interval (months) in each group and for the total sample are shown in Table 62 and Figure 20. The appointment interval was obtained by dividing the full duration of treatment by the number of scheduled appointments.

Table 62: Descriptive statistics for the appointment interval (months)

Group	N	Minimum	Maximum	Mean	SD
0.018''	77	0.85	5.40	1.80	0.59
0.022''	76	1.09	5.56	1.83	0.56
Total	153	0.85	5.56	1.81	0.57

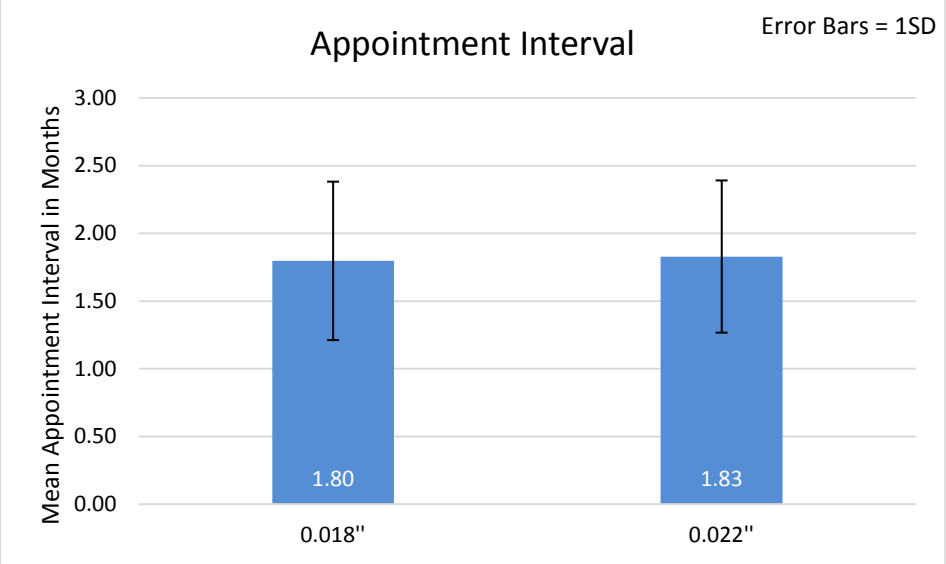

Figure 20: Mean appointment interval (months) in each group

6.2.1.3 Number of Appointments

The descriptive statistics for the number of appointments in each group and for the total sample are shown in Table 63 and Figure 21.

Table 63: Descriptive statistics for the number of appointments

Group	N	Minimum	Maximum	Median
0.018''	77	6	34	16
0.022''	76	6	36	17
Total	153	6	36	16

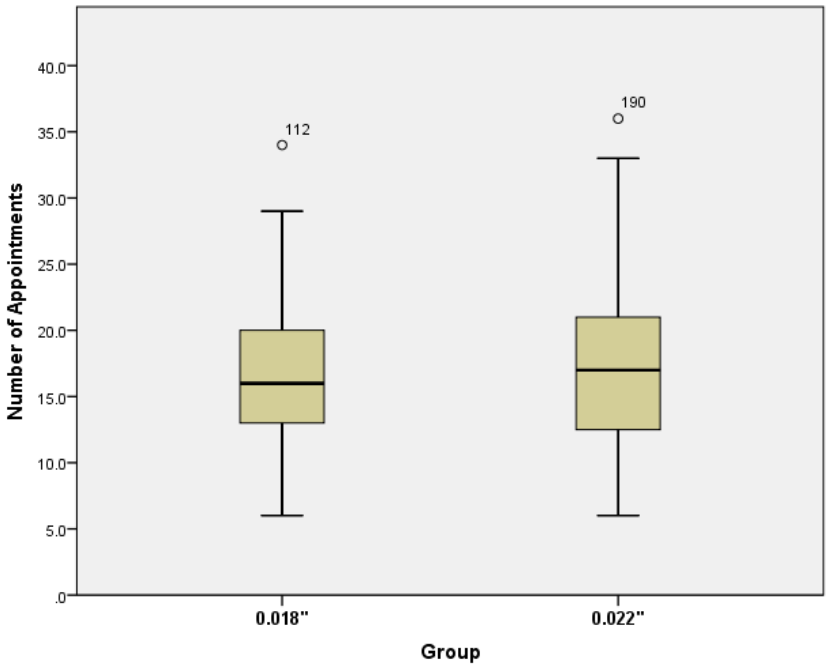

Figure 21: Boxplot for the median number of appointments in each group

6.2.1.4 Duration of Treatment

The descriptive statistics for the duration of treatment, duration of levelling and alignment stage, and duration of working and finishing stage (months) in each group and for the total sample are shown in Table 64 and Figures 22 and 23.

Table 64: Descriptive statistics for the durations of treatment (months)

Category	Group	N	Minimum	Maximum	Mean	SD
Duration of Overall Treatment	**0.018''**	77	13.71	53.92	29.26	9.53
	0.022''	76	8.75	66.35	31.17	12.26
	Total	153	8.75	66.35	30.21	10.98
Duration of Levelling and Alignment Stage	**0.018''**	77	4.60	24.13	11.82	5.02
	0.022''	76	2.99	33.21	11.75	6.19
	Total	153	2.99	33.21	11.78	5.61
Duration of Working and Finishing Stage	**0.018''**	77	1.38	40.80	17.44	9.09
	0.022''	76	1.15	50.47	19.42	11.65
	Total	153	1.15	50.47	18.42	10.45

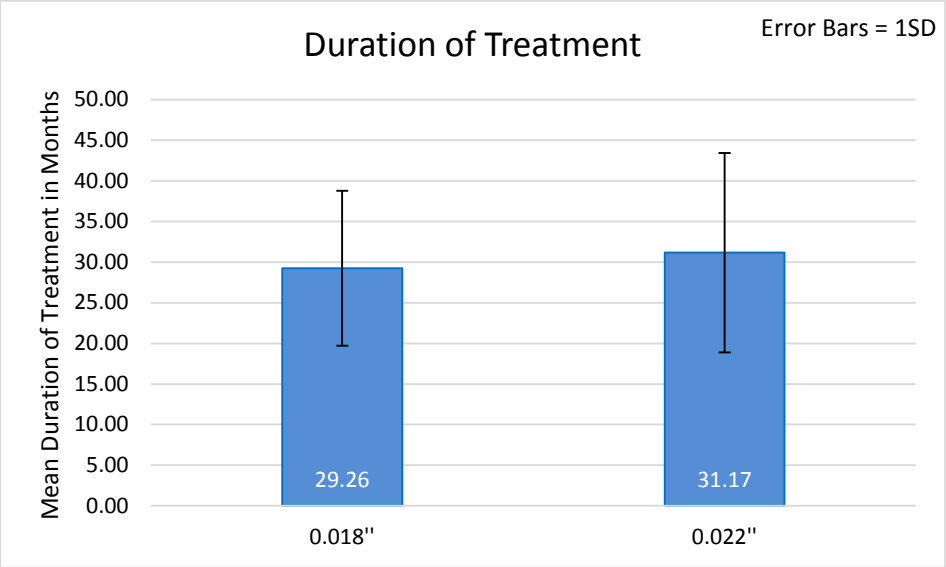

Figure 22: Mean duration of treatment (months) in each group

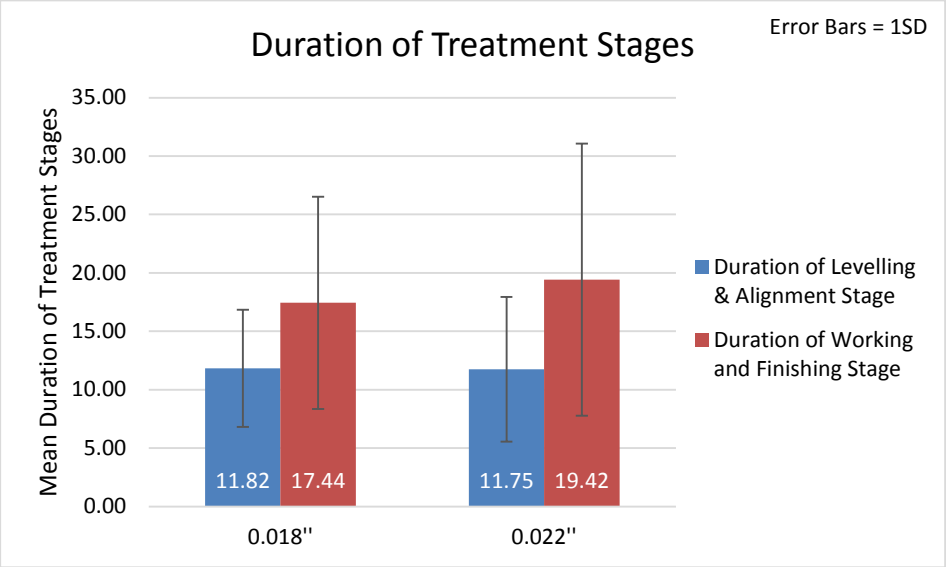

Figure 23: Mean duration of treatment stages (months) in each group

6.2.2 Comparison of Duration of Treatment and Number of Appointments

An independent samples t-test was used to detect the effect of bracket slot size on the mean duration of treatment and number of appointments. The same test was undertaken to compare the duration of the levelling and alignment stage and the working and finishing stage between the appliance groups (Table 65). Since four tests were performed addressing the same question and using the same data, a Bonferroni correction was applied changing the p-value from 0.05 to 0.0125 (0.05/4 = 0.0125). For the overall duration of treatment, the mean difference between the 0.018'' group (29.26 months) and 0.022'' group (31.17 months) was 1.905 months and this was not statistically significant (t (151) = -1.074, p = 0.285 with a 95% Confidence Interval of Difference: -5.410 to 1.601). Similarly, no statistically significant differences were found between the appliance groups for the number of appointments and durations of the main stages of treatment.

It is important to note that normality was not tested due to the large sample size as the data were considered within "the central limit theorem" (Field, 2013; Stewart, 2016). Homogeneity of variance was assessed using a Levene's test and was found to be non-significant (Table 65). For the duration of treatment, outliers were explored by calculating how many scores exceeded ±1.96 standard deviations from the mean of their respective groups. In both groups, the number of scores exceeding this value was consistent with what would be expected with a sample this size. However, in 0.022'' group all of the five extreme scores were above the mean (Figure 24). The data were analysed using t-tests and there was no significant difference between the two groups. Since there was concern over whether the extreme scores from the 0.022'' group were biasing the test, those five scores were removed and the test was re-run. The test became more non-significant (p = 0.844). It was also decided to check the results using a non-

parametric Mann-Whitney U test. The Mann-Whitney test agreed with the non-significant results of the t-tests, both when the outliers were excluded or included.

Table 65: Independent samples t-test for the durations of treatment and number of appointments between the groups

Variables	Levene's Test for Equality of Variances		t-test for Equality of Means						
	F	Sig.	t	df	p	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
								Lower	Upper
Duration of Treatment	1.566	0.213	-1.074	151	0.285	-1.905	1.774	-5.410	1.601
Number of Appointments	1.143	0.287	-0.626	151	0.533	-0.617	0.987	-2.567	1.332
Duration of Levelling & Alignment Stage	0.740	0.391	0.086	151	0.931	0.078	0.910	-1.720	1.877
Duration of Working & Finishing Stage	2.327	0.129	-1.175	151	0.242	-1.983	1.688	-5.318	1.352

*Significance level < 0.0125

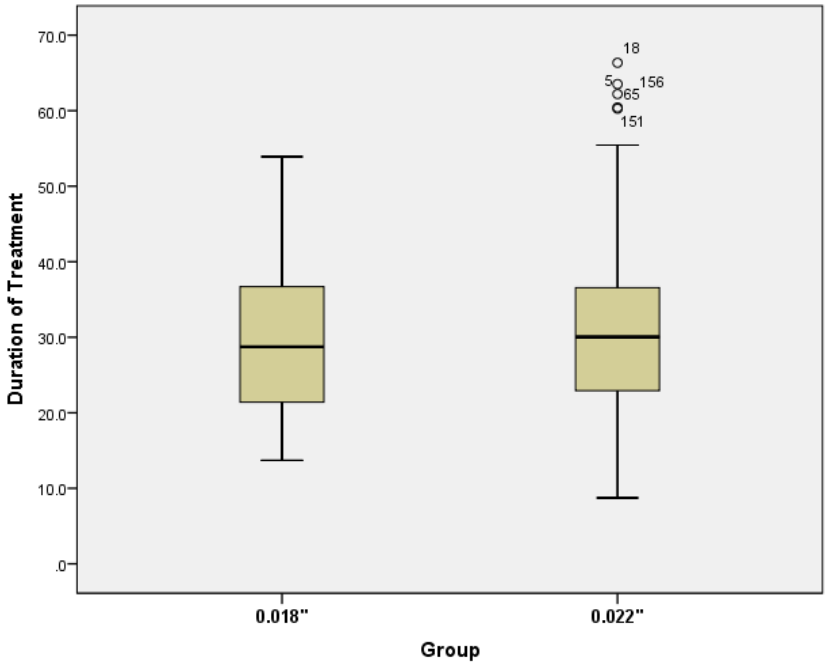

Figure 24: Boxplot for the duration of treatment (months) in each group showing the outliers

6.2.3 Factors Influencing Duration of Treatment

In order to identify the predictors that influenced treatment duration, 16 independent variables (Table 66) that have the potential to influence treatment duration were included in the same model and a multiple linear regression analysis was undertaken.

Table 66: Independent variables with potential influence on treatment duration used for multiple linear regression analysis

Patient-Related Factors	
Demographic Factors	Age
	Gender
Patients Characteristics	Type of malocclusion
	Presence or absence of impacted teeth
	Severity of malocclusion (Pre-treatment PAR index)
Patient Cooperation	Number of failed appointments
	Number of emergency appointments
	Number of debonded brackets/“broken” appliance
Treatment-Related Factors	
Treatment Modality	Presence or absence of extracted teeth
	Presence or absence of anchorage device
	Presence or absence of intermaxillary elastics
	Type of bracket slot (0.018’’ or 0.022’’)
	Was archwire sequence followed
	Number of clinicians (one or more than one)
Quality of Treatment	Degree of case improvement (% PAR reduction)
	Quality of treatment outcome (ABO CR-EVAL index)

6.2.3.1 Regression Model

In this model, all predictor variables from Table 66 were included. A multiple linear regression using backwards stepwise deletion was carried out. The model was inspected for violation of the assumption of independence using the Durbin Watson statistic and multicollinearity using the VIF and Tolerance statistics. Neither of these were found to be problematic. Additionally, the ZPRED/ZRESID plot was used to assess the model for violation of the assumption of homogeneity and Cook's distance was calculated for each subject to identify individuals who were unduly biasing the model and no anomalies were observed. Therefore, no transformation was applied to the dependent variable.

The model showed that total treatment duration could be predicted significantly by five factors: *age at bonding*, whether patients had a *Class II division 2 malocclusion, number of failed appointments, number of emergency appointments,* and whether *patients had been treated by more than one clinician*. The predictive power of this model was with an adjusted R^2 of 0.330 indicating that it was accounting for about 33% of the variance in treatment duration (Table 67 and Figures 25 and 26).

Table 67: Multiple linear regression analysis presenting factors influenced duration of treatment

Regression Model	Unstandardized Coefficients		Standardized Coefficients	t	p	95% Confidence Interval for B		Collinearity Statistics	
	B	**SE**	**Beta**			**Lower Bound**	**Upper Bound**	**Tolerance**	**VIF**
(Constant)	15.261	2.134		7.151	**0.000*** **	11.041	19.482		
Age at Bonding	0.395	0.092	0.309	4.302	**0.000*** **	0.213	0.577	0.919	1.088
Class II Div 2	4.741	1.888	0.176	2.511	**0.013***	1.007	8.475	0.964	1.037
Number of Failed Appointments	1.323	0.233	0.417	5.674	**0.000*** **	0.862	1.784	0.879	1.138
Number of Emergency Appointments	0.950	0.386	0.178	2.459	**0.015****	0.186	1.715	0.912	1.097
Number of Clinicians	4.071	1.844	0.163	2.208	**0.029***	0.424	7.717	0.869	1.151

*Significance level < 0.05

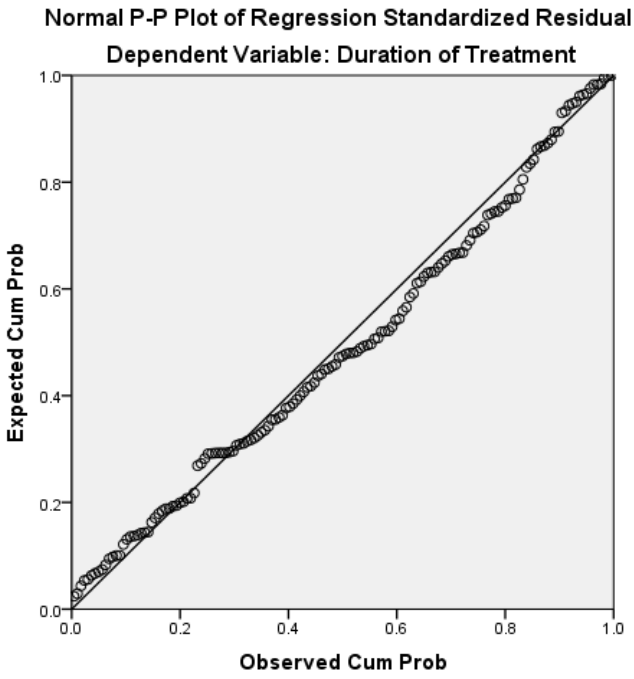

Figure 25: Normal P-P plot for multiple linear regression analysis of factors influenced duration of treatment

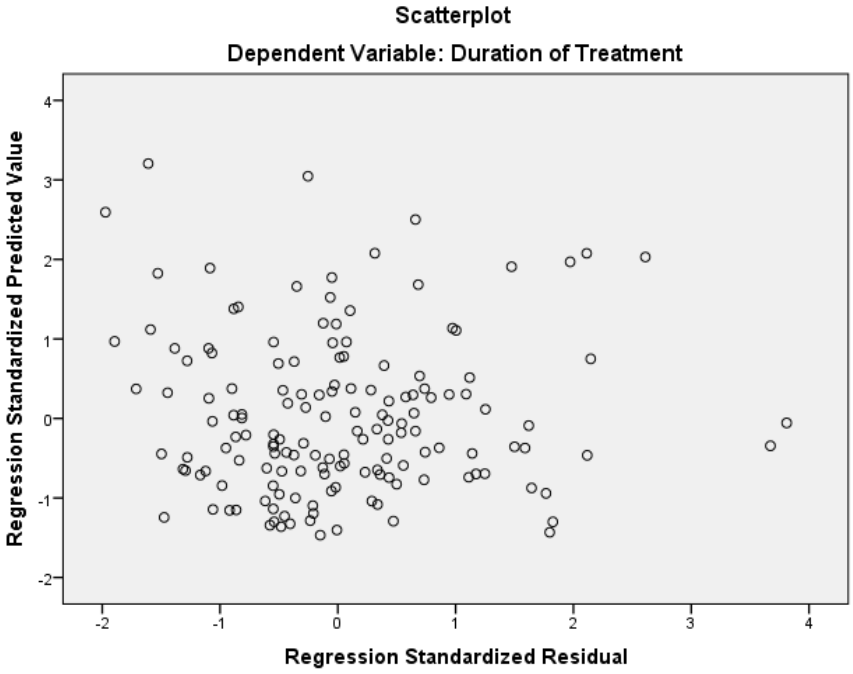

Figure 26: ZPRED/ZRESID plot for multiple linear regression analysis of factors influenced duration of treatment

6.3 QUALITY OF TREATMENT

6.3.1 PAR Score/Descriptive Statistics

The descriptive statistics for the post-treatment PAR score and percentage PAR score reduction in each group and for the total sample are shown in Table 68 and Figures 27 and 28.

Table 68: Descriptive statistics for the post-treatment PAR score and percentage PAR score reduction

Variables	Group	N	Minimum	Maximum	Mean	SD
Post-treatment PAR	**0.018’’**	73	2	34	7.37	5.14
	0.022’’	70	2	28	6.04	4.41
	Total	143	2	34	6.72	4.82
% PAR Reduction	**0.018’’**	73	9.52%	94.12%	74.07%	18.12
	0.022’’	70	11.11%	96.72%	77.13%	18.22
	Total	143	9.52%	96.72%	75.57%	18.17

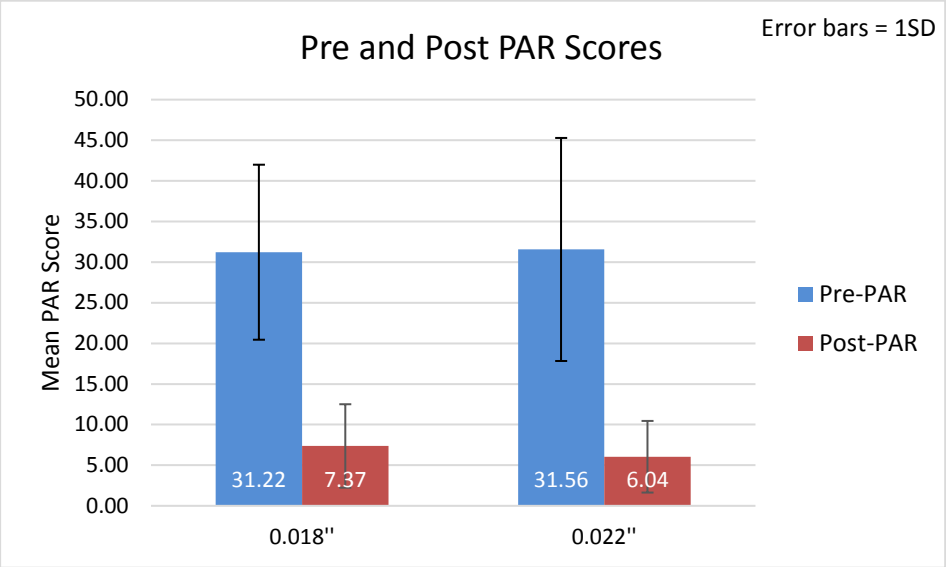

Figure 27: Mean pre-treatment and post-treatment PAR scores in each group

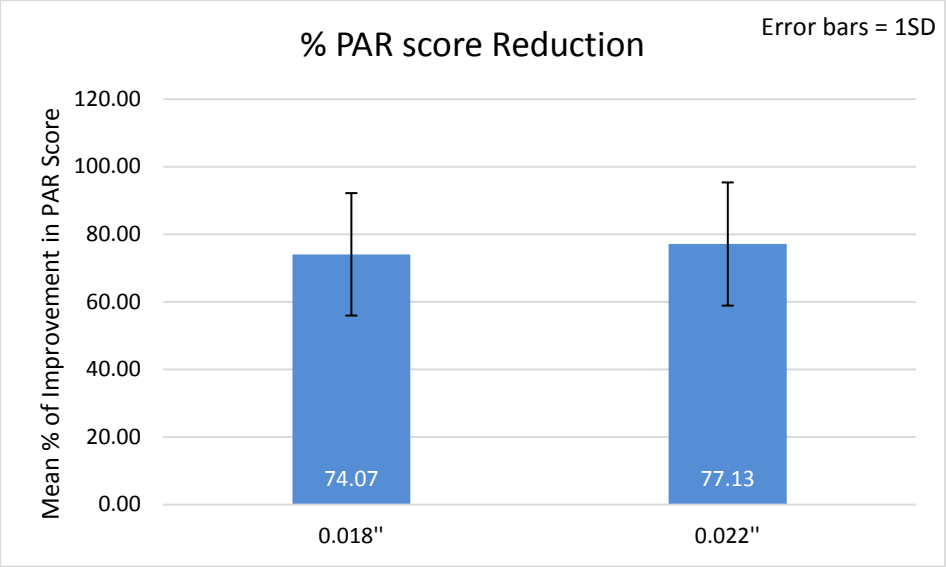

Figure 28: Mean percentage PAR score reduction in each group

6.3.2 PAR Score/Comparison between 0.018'' and 0.022'' Groups

A comparison between the 0.018-inch and 0.022-inch slot bracket groups was undertaken using an independent samples t-test as shown in Table 69. Two extreme outliers were removed from the post-treatment PAR sample (one from each group) before undertaking the analysis to avoid their biasing effect. The difference in the post-treatment PAR scores showed marginal significance between groups with p = 0.050, while no significant difference was found in the percentage PAR score reduction between the appliance groups (p = 0.316). A Bonferroni correction was applied to these two tests and the p significance level changed from 0.05 to 0.025.

Table 69: Independent samples t-test for the post-treatment PAR score and percentage PAR score reduction between the groups

Variables	t	df	p	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
Post-treatment PAR	1.980	139	**0.050**	1.275	0.644	0.002	2.549
% PAR Reduction	-1.006	141	0.316	-3.059	3.040	-9.068	2.950

*Significance level < 0.025

6.3.3 ABO CR-EVAL Score/Reliability of the Results

Calibration with the ABO CR-EVAL was considered sufficient after several repetitions of the measurement using the calibration kit until the results were comparable with the scoring sheet results provided by the ABO. The ICC revealed an excellent (0.95) intra-examiner agreement for the ABO CR-EVAL measurement.

6.3.4 ABO CR-EVAL Score/Descriptive Statistics

The descriptive statistics for the total ABO CR-EVAL post-treatment score and its components in each group and for the total sample are shown in Table 70 and Figure 29.

Table 70: Descriptive statistics for the ABO CR-EVAL scores

Variables	0.018'' (N = 73)		0.022'' (N = 72)		Total (N = 145)	
	Mean	SD	Mean	SD	Mean	SD
TOTAL ABO CR-EVAL	34.71	9.52	34.49	11.02	34.60	10.26
Alignment/Rotation	8.59	2.73	9.14	3.25	8.86	3.00
Marginal Ridges	4.42	1.88	5.22	2.87	4.82	2.45
Buccolingual Inclination	4.77	2.91	4.75	3.21	4.76	3.05
Overjet	4.38	3.27	3.85	3.10	4.12	3.19
Occlusal Contacts	6.58	4.16	6.35	4.35	6.46	4.24
Occlusal Relationships	5.30	3.63	4.76	3.33	5.03	3.48
Interproximal Contacts	0.67	1.50	0.42	1.12	0.54	1.33

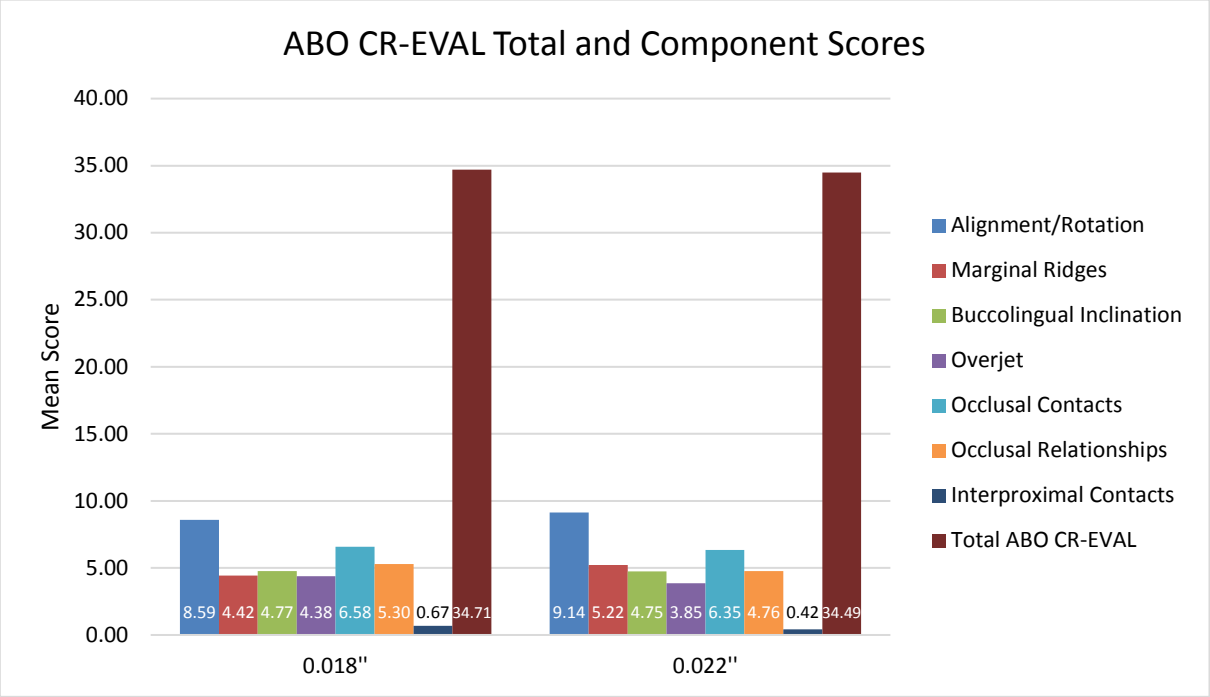

Figure 29: Mean ABO CR-EVAL scores in each group

6.3.5 ABO CR-EVAL Score/Comparison between 0.018'' and 0.022'' Groups

A comparison between the 0.018-inch and 0.022-inch slot bracket groups was undertaken using an independent samples t-test and Mann-Whitney U test (for interproximal contact component due to heterogeneity) as shown in Tables 71 and 72. When looking at the components of the Total CR-EVAL score, multiple tests (six t-tests and one Mann-Whitney U test) were conducted. Since they were carried out on the same data and addressing the same hypothesis, it was necessary to apply a correction to the criterion p-value to prevent family-wise error rate inflation. Since seven tests were carried out, the criterion p-value was changed from 0.05 to 0.0071 (0.05/7). Only tests which had a p-value lower than 0.0071 can be considered significant. No significant differences were found in the total scores and the components of the ABO CR-EVAL between the groups.

A Chi-square was carried out comparing the three ABO CR-EVAL categories (High, Medium, and Low) between 0.018'' and 0.022'' groups (Table 73). Because of low expected frequencies in the Low ABO category, a Fisher's exact test was used to compute the significance of the Chi-Square. No significant differences were found within each category of the ABO CR-EVAL between the appliance groups.

Table 71: Independent samples t-test for the ABO CR-EVAL scores between the groups

Variables	t	df	p	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
						Lower	Upper
TOTAL ABO CR-EVAL	0.132	143	0.895	0.2262	1.7093	-3.1526	3.6050
Alignment/Rotation	-1.104	143	0.272	-0.5498	0.4981	-1.5345	0.4348
Marginal Ridges	-1.975	122.035	0.050	-0.7976	0.4037	-1.5968	0.0017
Buccolingual Inclination	0.034	143	0.973	0.0171	0.5082	-0.9874	1.0216
Overjet	1.013	143	0.313	0.5363	0.5294	-0.5101	1.5827
Occlusal Contacts	0.323	143	0.747	0.2281	0.7066	-1.1686	1.6249
Occlusal Relationships	0.929	143	0.355	0.5375	0.5788	-0.6066	1.6815

*Significance level < 0.0071

Table 72: Independent samples Mann-Whitney U test for the interproximal contact scores between the groups

Variable	Group	N	Mean Rank	Test Statistics	Standard Error	P
Interproximal Contact	**0.018''**	73	76.84	2348.000	187.530	0.135
	0.022''	72	69.11			

*Significance level < 0.0071

Table 73: Chi-square for the categories of ABO CR-EVAL between the groups

Category	Group	N	% within Each Group	Pearson Chi-Square	df	p (Fisher's Exact Test)
Low ABO (< 20)	**0.018''**	3	4.1%	0.170	2	1.000
	0.022''	4	5.6%			
Medium ABO (20-30)	**0.018''**	22	30.1%			
	0.022''	21	29.2%			
High ABO (> 30)	**0.018''**	48	65.8%			
	0.022''	47	65.3%			

*Significance level < 0.05

6.3.6 Incisor Inclination/Reliability of the Results

The ICC revealed excellent intra-examiner agreements for the U1-PP angle (0.97) and L1-MP angle (0.98).

6.3.7 Incisor Inclination/Descriptive Statistics

The inclination angles (˚) for the U1-PP and L1-MP pre-treatment and near end of treatment in each group and for the total sample are described in Table 74 and Figures 30 and 31.

Table 74: Descriptive statistics for the U1-PP and L1-MP angles (˚)

Category	Group	N	Pre-treatment		Near End of Treatment	
			Mean	SD	Mean	SD
U1-PP	0.018''	60	107.3	9.4	110.2	7.5
	0.022''	68	108.6	8.3	110.1	7.6
	Total	128	108.0	8.8	110.2	7.5
L1-MP	0.018''	60	91.4	7.9	94.1	7.9
	0.022''	68	92.9	7.6	94.3	7.9
	Total	128	92.2	7.7	94.2	7.9

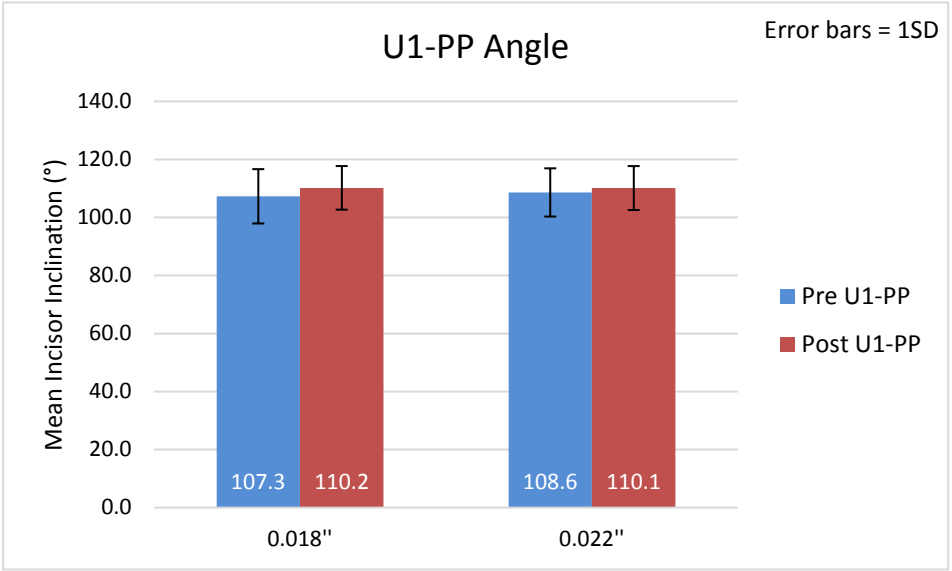

Figure 30: Mean U1-PP angle (◦) in each group

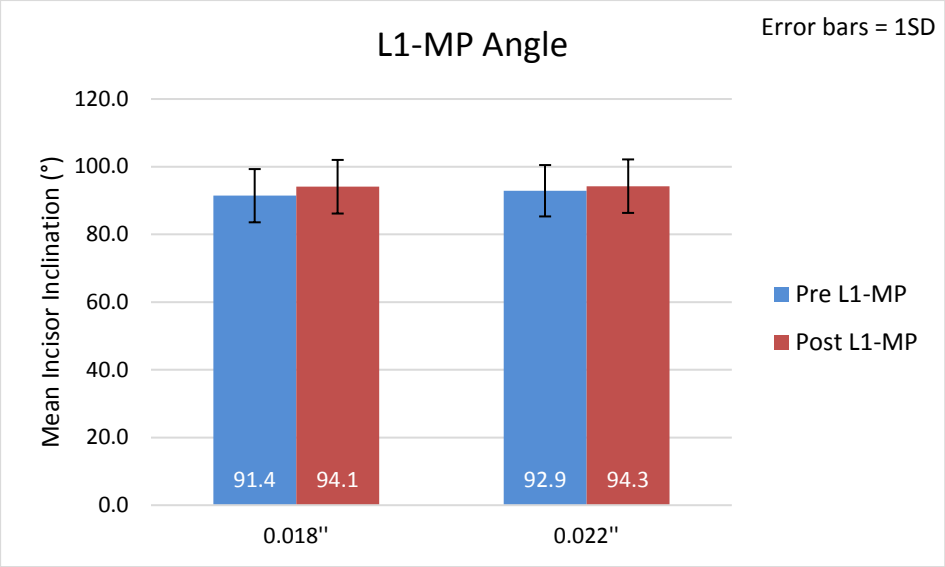

Figure 31: Mean L1-MP angle (°) in each group

6.3.8 Incisor Inclination/Comparison between 0.018'' and 0.022'' Groups

A two-way ANOVA test was used to compare the incisor inclination between pre-treatment and near end of treatment and between 0.018'' and 0.022'' groups. This was performed separately for both the maxillary and mandibular incisor inclination (Table 75 and Figures 32 and 33). In both U1-PP and L1-MP angles, a two (pre/near end) by two (group) mixed factorial ANOVA revealed that there was no significant difference between the two appliance groups, nor was there a significant interaction between group and pre-near end. Nevertheless, there were statistically significant differences of incisor inclination between pre-treatment and near end treatment [F (1, 126) = 9.365, p = 0.003 for U1-PP angle and F (1, 126) = 7.461, p = 0.007 for L1-MP angle].

Table 75: Two-way ANOVA test for the U1-PP and L1-MP angles between the groups

Category	Source	df	F	p
U1-PP	**Pre-Near End of Treatment**	1	9.365	**0.003****
	Pre-Near End * Group	1	0.937	0.335
	Pre-Near End * Group (within subjects)	1	0.251	0.617
L1-MP	**Pre-Near End of Treatment**	1	7.461	**0.007****
	Pre-Near End * Group	1	0.783	0.378
	Pre-Near End * Group (within subjects)	1	0.482	0.489

*Significance level < 0.05

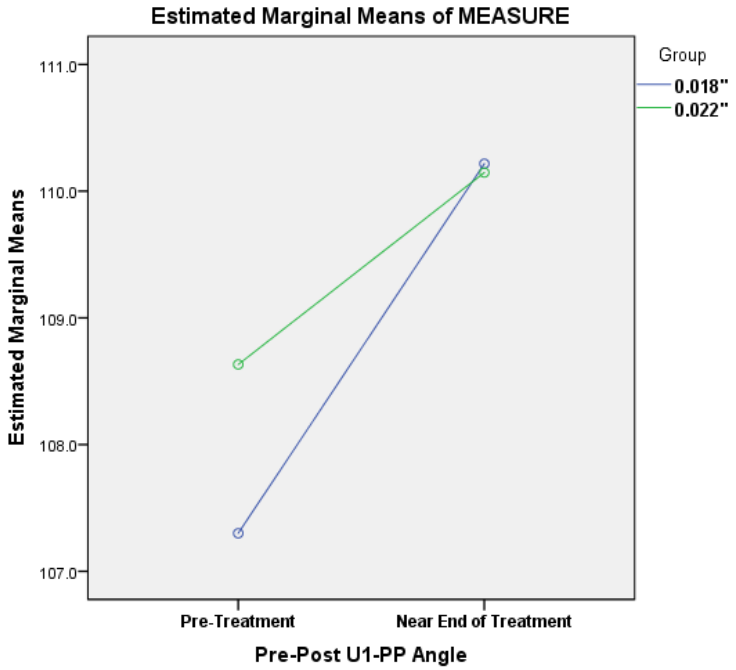

Figure 32: Variation of the U1-PP angle in each group

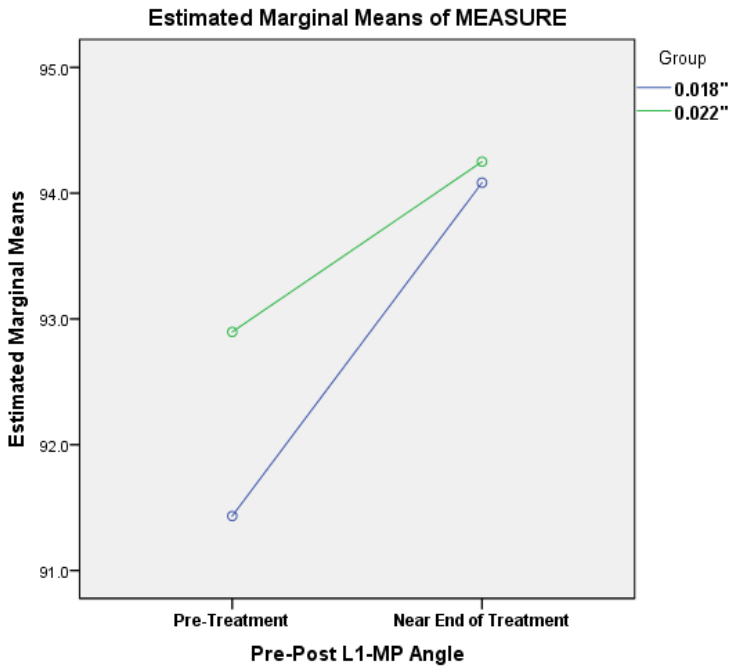

Figure 33: Variation of the L1-MP angle in each group

6.3.9 Anchorage Loss/Reliability of the Results

The ICC values of 0.98 for inter-examiner reliability and 0.97 for intra-examiner reliability indicated high levels of agreement and near-perfect reproducibility of the measurements.

6.3.10 Anchorage Loss/Descriptive Statistics

The descriptive statistics for the right and left anchorage loss (mm) in each group and for the total sample are presented in Table 76 and Figure 34.

Table 76: Descriptive statistics for the anchorage loss (mm)

Side	Group	N	Minimum	Maximum	Mean	SD
Left Side	**0.018''**	41	0.02	7.85	3.30	2.03
	0.022''	33	-1.75	6.66	3.47	1.69
	Total	74	-1.75	7.85	3.38	1.87
Right Side	**0.018''**	41	-0.34	8.60	3.86	2.15
	0.022''	33	0.64	10.01	3.73	1.87
	Total	74	-0.34	10.01	3.80	2.02

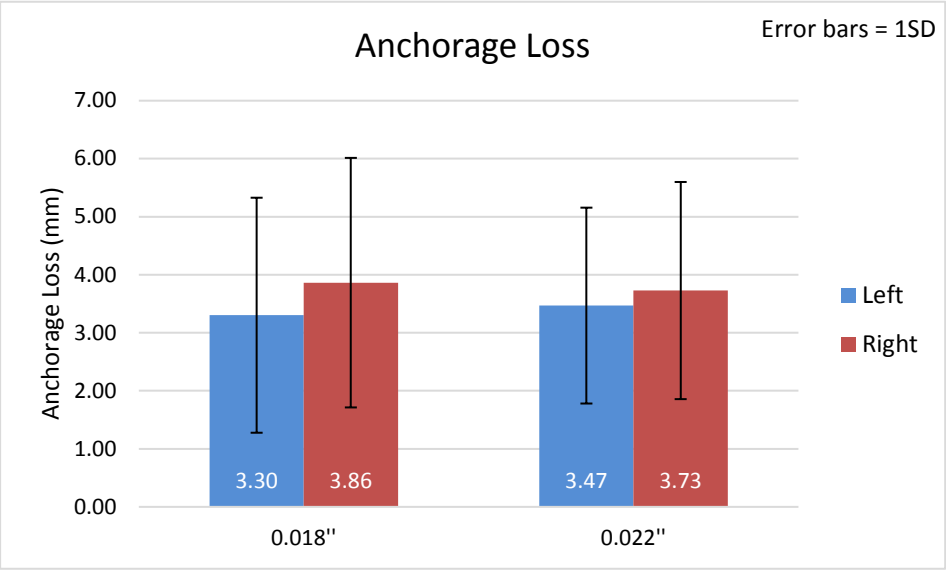

Figure 34: Mean anchorage loss (mm) in each group

6.3.11 Anchorage Loss/Comparison between 0.018’’ and 0.022’’ Groups

A two-way ANOVA test was used to compare the anchorage loss between the right and left sides and between 0.018’’ and 0.022’’ groups (Table 77). No statistically significant difference was found between the two appliance groups where $F(1, 72) = 0.001$, $p = 0.970$. Similarly, there was no statistically significant difference for the interaction between group and side, nor for the effect of left-right sides ($p > 0.05$).

Normality was not an issue due to the large sample size. Homogeneity was tested using Levene’s test and no anomalies were observed. The data were also assessed for extreme outliers and only two cases were observed with Studentised Residuals exceeding 3SD which were not considered problematic. The data were inspected for overly influential cases using Cook’s value and none were found to exceed 1 so there were no excessively influential cases.

In order to ensure that there were no significant differences between the groups, the baseline variables (age, gender, type of malocclusion, and presence or absence of anchorage device) for the selected cases were compared between the groups using an independent samples t-test for continuous variables and Chi-square with Fisher's exact tests for categorical variables. There was only significant difference in the presence or absence of anchorage devices ($p = 0.050$). Therefore, a new set of data excluding cases with anchorage devices was created and compared (Tables 77 and Figure 35). This included 23 subjects in the 0.018’’ group and 26 subjects in the 0.022’’ group. The mean anchorage loss value for the 0.022’’ group was slightly higher than the 0.018’’ group in this subset, but it was not statistically significant: $F(1, 47) = 0.777$, $p = 0.383$ (Table 77).

Table 77: Two-way ANOVA test for the anchorage loss between the groups

Category	Source	df	F	p
All Selected Cases (N = 74)	**Side**	1	3.382	0.070
	Side * Group	1	0.459	0.500
	Group	1	0.001	0.970
Cases without Anchorage Devices (N = 49)	**Side**	1	3.268	0.077
	Side * Group	1	0.119	0.732
	Group	1	0.777	0.383

*Significance level < 0.05

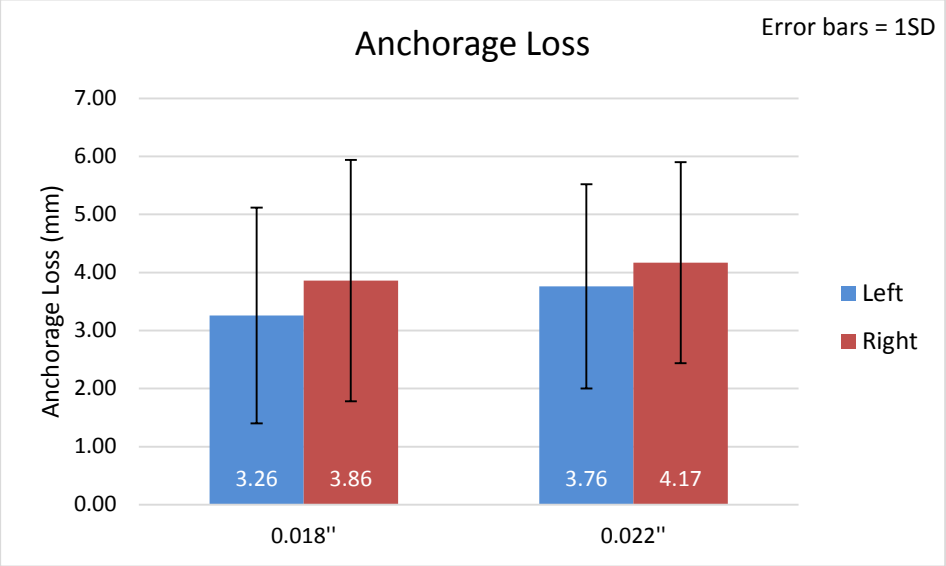

Figure 35: Mean anchorage loss (mm) in each group (cases without anchorage devices)

6.3.12 Patient Perception of Fixed Appliance Orthodontic Treatment

6.3.12.1 Patient Expectations

Patient expectations were compared between the 0.018-inch slot and 0.022-inch slot bracket groups using the Pre-treatment Questionnaire. Descriptive statistics for frequency distribution and percentages of the answers and Chi-square with Fisher's exact tests between groups are presented in Table 78. Only one significant difference was found between groups in question “To make it easier to bite into food”.

6.3.12.2 Patient Experiences

The Smiles-Better (Orthodontic Experience) Questionnaire was used to collect data regarding patient experience during orthodontic treatment. Descriptive statistics for frequency distribution and percentages of the answers and Chi-square with Fisher's exact tests between groups are presented in Table 79. No significant differences were found between 0.018’’ and 0.022’’ group patients in their experiences with fixed appliance orthodontic treatment.

Some cases in the Pre-treatment and Orthodontic Experience Questionnaires were deleted from the analysis because the expected frequencies in the Chi-square from their responses were below 1 which causes problems even when using Fisher’s exact test (i.e. they were the only people to issue responses in that category).

6.3.12.3 Patient Satisfaction

6.3.12.3.1 Post-Treatment Questionnaire

Post-treatment Questionnaire was used to compare patient satisfaction with fixed appliance orthodontic treatment between patients with 0.018-inch slot brackets and those with 0.022-inch slot brackets. Descriptive statistics for frequency distribution and percentages of the answers and Chi-square with Fisher's exact tests between groups are

presented in Table 80. Only one significant difference was found between groups in item “It has helped my back teeth fit together” where more patients in the 0.022-inch slot bracket group selected the “No better” answer option.

6.3.12.3.2 IOTN AC

Patients’ self-assessment of their dental aesthetics was compared using the pre-treatment and post-treatment IOTN AC. A highly statistically significant improvement in aesthetics was noted between pre-treatment and post-treatment IOTN in both groups and for the total sample as indicated by Wilcoxon signed-rank test (Table 81). However, no statistically significant differences were found between the 0.018’’ and 0.022’’ groups as shown in Table 82 using Mann-Whitney U test. Due to a series of five non-parametric tests investigating different aspects of the IOTN data, a Bonferroni correction was applied to control for family-wise error. Accordingly, the thresholds for declaring a result significant at the 0.05 and 0.01 levels became 0.05/5 = 0.01 and 0.01/5 = 0.002, respectively.

Table 78: Distribution and comparison of answers in the Pre-treatment Questionnaire between the groups (Patient Expectations)

Question	Group	Valid	Missing	Deleted	Not a reason 1	2	3	Very much a reason 4	Pearson Chi-Square	df	p (Fisher's Exact Test)
To make my teeth look nicer	**0.018''**	77	0	0		2 (2.6%)	11 (14.3%)	64 (83.1%)	0.346	2	0.832
	0.022''	75	0	1		3 (4.0%)	12 (16.0%)	60 (80.0%)			
To make my smile nicer	**0.018''**	77	0	0	4 (5.2%)	2 (2.6%)	23 (29.9%)	48 (62.3%)	3.189	3	0.380
	0.022''	76	0	0	3 (3.9%)	7 (9.2%)	23 (30.3%)	43 (56.6%)			
To make my face look better	**0.018''**	77	0	0	22 (28.6%)	22 (28.6%)	18 (23.4%)	15 (19.5%)	1.665	3	0.650
	0.022''	76	0	0	16 (21.1%)	26 (34.2%)	16 (21.1%)	18 (23.7%)			
To make me look better	**0.018''**	76	1	0	10 (13.2%)	13 (17.1%)	25 (32.9%)	28 (36.8%)	2.151	3	0.541
	0.022''	76	0	0	9 (11.8%)	18 (23.7%)	18 (23.7%)	31 (40.8%)			
To feel more confident	**0.018''**	77	0	0	8 (10.4%)	17 (22.1%)	20 (26.0%)	32 (41.6%)	1.166	3	0.759
	0.022''	76	0	0	11 (14.5%)	13 (17.1%)	18 (23.7%)	34 (44.7%)			
To make me feel better about myself	**0.018''**	77	0	0	9 (11.7%)	16 (20.8%)	24 (31.2%)	28 (36.4%)	0.086	3	1.000
	0.022''	76	0	0	10 (13.2%	16 (21.1%)	23 (30.3%)	27 (35.5%)			
To make me feel better about going out	**0.018''**	77	0	0	33 (42.9%)	14 (18.2%)	19 (24.7%)	11 (14.3%)	3.212	3	0.370
	0.022''	76	0	0	28 (36.8%)	19 (25.0%)	13 (17.1%)	16 (21.1%)			

Question	Group	Valid	Missing	Deleted	Not a reason 1	2	3	Very much a reason 4	Pearson Chi-Square	df	p (Fisher's Exact Test)
To make it easier to get on with people	**0.018''**	77	0	0	67 (87.0%)	9 (11.7%)		1 (1.3%)	2.905	2	0.273
	0.022''	75	0	1	68 (90.7%)	4 (5.3%)		3 (4.0%)			
To help my top and bottom teeth fit together	**0.018''**	77	0	0	5 (6.5%)	11 (14.3%)	27 (35.1%)	34 (44.2%)	2.299	3	0.521
	0.022''	76	0	0	8 (10.5%)	11 (14.5%)	19 (25.0%)	38 (50.0%)			
To help my front teeth fit together	**0.018''**	77	0	0	7 (9.1%)	8 (10.4%)	18 (23.4%)	44 (57.1%)	3.601	3	0.310
	0.022''	76	0	0	7 (9.2%)	14 (18.4%)	22 (28.9%)	33 (43.4%)			
To help my back teeth fit together	**0.018''**	77	0	0	19 (24.7%)	15 (19.5%)	21 (27.3%)	22 (28.6%)	1.850	3	0.622
	0.022''	75	1	0	25 (33.3%)	14 (18.7%)	15 (20.0%)	21 (28.0%)			
To make it easier to bite into food	**0.018''**	76	1	0	40 (52.6%)	**14 (18.4%)**	15 (19.7%)	7 (9.2%)	8.188	3	**0.042***
	0.022''	76	0	0	31 (40.8%)	**28 (36.8%)**	8 (10.5%)	9 (11.8%)			
To help me chew food better	**0.018''**	77	0	0	41 (53.2%)	18 (23.4%)	14 (18.2%)	4 (5.2%)	1.467	3	0.706
	0.022''	76	0	0	35 (46.1%)	24 (31.6%)	14 (18.4%)	3 (3.9%)			

Table 79: Distribution and comparison of answers in the Orthodontic Experience Questionnaire between the groups (Patient Experiences)

Question	Group	Valid	Missing	Deleted	Improved	No Change	Worse	Pearson Chi-Square	df	Sig. (Fisher's Exact Test)
Eating	**0.018''**	77	0	0	11 (14.3%)	36 (46.8%)	30 (39.0%)	0.521	2	0.830
	0.022''	76	0	0	8 (10.5%)	38 (50.0%)	30 (39.5%)			
Appearance	**0.018''**	77	0	0	31 (40.3%)	34 (44.2%)	12 (15.6%)	1.697	2	0.440
	0.022''	76	0	0	36 (47.4%)	33 (43.4%)	7 (9.2%)			
If you have experienced teasing how has it affected your schoolwork?	**0.018''**	59	18	0	2 (3.4%)	57 (96.6%)	0 (0.0%)	0.486	1	0.683
	0.022''	66	10	0	4 (6.1%)	62 (93.3%)	0 (0.0%)			
How have any changes in your appearance affected your friendships?	**0.018''**	77	0	0	6 (7.8%)	71 (92.2%)	0 (0.0%)	0.153	1	0.776
	0.022''	73	2	1	7 (9.6%)	66 (90.4%)	0 (0.0%)			
If you have experienced teasing how has it affected your friendships?	**0.018''**	72	5	0	4 (5.6%)	68 (94.4%)	0 (0.0%)	0.109	1	1.000
	0.022''	69	7	0	3 (4.3%)	66 (95.7%)	0 (0.0%)			
How have any changes in your appearance affected your relationship with your family?	**0.018''**	77	0	0	6 (7.8%)	71 (92.2%)	0 (0.0%)	0.348	1	0.746
	0.022''	74	1	1	4 (5.4%)	70 (94.6%)	0 (0.0%)			
If you have experienced teasing how has it affected your relationship with your family?	**0.018''**	74	3	0	2 (2.7%)	71 (95.9%)	1 (1.4%)	2.277	2	0.518
	0.022''	69	7	0	0 (0.0%)	67 (97.1%)	2 (2.9%)			
					Less	**No Change**	**Worse**			
I am teased	**0.018''**	71	6	0	24 (33.8%)	41 (57.7%)	6 (8.5%)	3.067	2	0.199
	0.022''	75	1	0	22 (29.3%)	51 (68.0%)	2 (2.7%)			

Question	Group	Valid	Missing	Deleted	Not At All	A Little	A Lot	Pearson Chi-Square	df	Sig. (Fisher's Exact Test)
Sore teeth	**0.018''**	77	0	0	5 (6.5%)	65 (84.4%)	7 (9.1%)	4.985	2	0.083
	0.022''	76	0	0	12 (15.8%)	53 (69.7%)	11 (14.5%)			
Soreness in your mouth	**0.018''**	77	0	0	20 (26.0%)	53 (68.8%)	4 (5.2%)	0.360	2	0.885
	0.022''	76	0	0	23 (30.3%)	49 (64.5%)	4 (5.3%)			
Soreness from rubbing	**0.018''**	77	0	0	17 (22.1%)	49 (63.6%)	11 (14.3%)	2.445	2	0.299
	0.022''	75	1	0	13 (17.3%)	56 (74.7%)	6 (8.0%)			
Feeling embarrassed	**0.018''**	77	0	1	64 (83.1%)	13 (16.9%)	0 (0.0%)	0.373	1	0.652
	0.022''	75	0	0	65 (86.7%)	10 (13.3%)	0 (0.0%)			
Keeping the brace clean is a nuisance	**0.018''**	77	0	0	33 (42.9%)	39 (50.6%)	5 (6.5%)	0.787	2	0.681
	0.022''	76	0	0	28 (36.8%)	41 (53.9%)	7 (9.2%)			
Sore teeth (Schoolwork)	**0.018''**	64	13	0	36 (56.3%)	28 (43.8%)	0 (0.0%)	0.607	1	0.483
	0.022''	70	5	1	44 (62.9%)	26 (37.1%)	0 (0.0%)			
Soreness in your mouth (Schoolwork)	**0.018''**	63	13	1	39 (61.9%)	24 (38.1%)	0 (0.0%)	2.519	1	0.137
	0.022''	71	5	0	53 (74.6%)	18 (25.4%)	0 (0.0%)			
Now that you are wearing a brace do you feel that your teeth are moving?	**0.018''**	77	0	0	3 (3.9%)	29 (37.7%)	45 (58.4%)	0.635	2	0.806
	0.022''	76	0	0	3 (3.9%)	24 (31.6%)	49 (64.5%)			
If you have had to make extra visits because your brace has broken, has this bothered you?	**0.018''**	61	16	0	35 (57.4%)	23 (37.7%)	3 (4.9%)	0.633	2	0.734
	0.022''	64	12	0	34 (53.1%)	28 (43.8%)	2 (3.1%)			

Question	Group	Valid	Missing	Deleted	I enjoy doing more…….	No different	I do less…….	Pearson Chi-Square	df	Sig. (Fisher's Exact Test)
Hobbies/Interests (Music)	**0.018''**	65	12	0	4 (6.2%)	58 (89.2%)	3 (4.6%)	1.568	2	0.513
	0.022''	57	19	0	3 (5.3%)	48 (84.2%)	6 (10.5%)			
					Yes	**No**	**Not Sure**			
Is wearing a brace what you expected?	**0.018''**	76	1	0	46 (60.5%)	15 (19.7%)	15 (19.7%)	0.926	2	0.651
	0.022''	73	3	0	42 (57.5%)	19 (26.0%)	12 (16.4%)			
					Yes	**No**				
Have you had any extra visits to the hospital because your brace has broken?	**0.018''**	76	1	0	42 (55.3%)	34 (44.7%)		1.713	1	0.241
	0.022''	73	3	0	48 (65.8%)	25 (34.2%)				
					Positive	**Neutral**	**Negative**			
Overall experience	**0.018''**	52	25	0	30 (57.7%)	19 (36.5%)	3 (5.8%)	1.327	2	0.543
	0.022''	58	18	0	28 (48.3%)	24 (41.4%)	6 (10.3%)			

Table 80: Distribution and comparison of answers in the Post-treatment Questionnaire between the groups (Patient Satisfaction)

Question	Group	Valid	Missing	Deleted	No better	A little better	Much better	Very much better	Pearson Chi-Square	df	Sig. (Fisher's Exact Test)
It has made my teeth look nicer	**0.018''**	71	6	0	0 (0.0%)	1 (1.4%)	7 (9.9%)	63 (88.7%)	2.294	2	0.328
	0.022''	70	6	0	0 (0.0%)	3 (4.3%)	11 (15.7%)	56 (80.0%)			
It has made my face look better	**0.018''**	71	6	0	8 (11.3%)	15 (21.1%)	16 (22.5%)	32 (45.1%)	1.624	3	0.642
	0.022''	70	6	0	6 (8.6%)	12 (17.1%)	22 (31.4%)	30 (42.9%)			
It has made me look better	**0.018''**	71	6	0	4 (5.6%)	9 (12.7%)	18 (25.4%)	40 (56.3%)	1.710	3	0.651
	0.022''	71	5	0	2 (2.8%)	13 (18.3%)	20 (28.2%)	36 (50.7%)			
It has made me more confident	**0.018''**	70	7	0	3 (4.3%)	11 (15.7%)	13 (18.6%)	43 (61.4%)	4.230	3	0.230
	0.022''	71	5	0	4 (5.6%)	13 (18.3%)	22 (31.0%)	32 (45.1%)			
It has made me feel better about myself	**0.018''**	71	6	0	5 (7.0%)	10 (14.1%)	12 (16.9%)	44 (62.0%)	7.553	3	0.053
	0.022''	71	5	0	3 (4.2%)	10 (14.1%)	26 (36.6%)	32 (45.1%)			
It has made me feel better about going out	**0.018''**	69	8	0	11 (15.9%)	12 (17.4%)	19 (27.5%)	27 (39.1%)	0.783	3	0.863
	0.022''	70	6	0	14 (20.0%)	14 (20.0%)	16 (22.9%)	26 (37.1%)			
It has made it easier to get on with people	**0.018''**	67	10	0	38 (56.7%)	17 (25.4%)	6 (9.0%)	6 (9.0%)	0.724	3	0.881
	0.022''	71	5	0	41 (57.7%)	15 (21.1%)	9 (12.7%)	6 (8.5%)			
It has helped my top and bottom teeth fit together	**0.018''**	70	7	0	1 (1.4%)	8 (11.4%)	22 (31.4%)	39 (55.7%)	2.115	3	0.608

Question	Group	Valid	Missing	Deleted	No better	A little better	Much better	Very much better	Pearson Chi-Square	df	Sig. (Fisher's Exact Test)
	0.022''	71	5	0	4 (5.6%)	6 (8.5%)	21 (29.6%)	40 (56.3%)			
It has helped my front teeth fit together	**0.018''**	70	7	0	2 (2.9%)	6 (8.6%)	19 (27.1%)	43 (61.4%)	2.816	3	0.447
	0.022''	71	5	0	4 (5.6%)	8 (11.3%)	25 (35.2%)	34 (47.9%)			
It has helped my back teeth fit together	**0.018''**	69	8	0	**1 (1.4%)**	9 (13.0%)	27 (39.1%)	32 (46.4%)	7.976	3	**0.041***
	0.022''	71	5	0	**10 (14.1%)**	10 (14.1%)	23 (32.4%)	28 (39.4%)			
It has made it easier to chew my food	**0.018''**	71	6	0	8 (11.3%)	18 (25.4%)	34 (47.9%)	11 (15.5%)	4.587	3	0.210
	0.022''	71	5	0	15 (21.1%)	23 (32.4%)	25 (35.2%)	8 (11.3%)			
It has made it easier to bite into food	**0.018''**	70	7	0	9 (12.9%)	20 (28.6%)	18 (25.7%)	23 (32.9%)	2.252	3	0.533
	0.022''	71	5	0	15 (21.1%)	16 (22.5%)	20 (28.2%)	20 (28.2%)			

Table 81: Related-samples Wilcoxon signed-rank test between the Pre- and Post-treatment IOTN AC

Group	Variables	N	Test Statistics	Standard Error	p
0.018’’	**Pre-IOTN**	70	0.000	155.953	**0.000*****
	Post-IOTN				
0.022’’	**Pre-IOTN**	71	0.000	170.291	**0.000*****
	Post-IOTN				
Total	**Pre-IOTN**	141	0.000	458.716	**0.000*****
	Post-IOTN				

*Significance level < 0.01

Table 82: Independent samples Mann-Whitney U test for the Pre- and Post-treatment IOTN AC between the groups

Variable	Group	N	Mean Rank	Test Statistics	Standard Error	p
Pre-IOTN	**0.018’’**	77	77.99	2850.000	270.449	0.779
	0.022’’	76	76.00			
Post-IOTN	**0.018’’**	70	72.17	2403.000	172.794	0.635
	0.022’’	71	69.85			

*Significance level < 0.01

6.4 BIOLOGICAL SIDE EFFECTS OF TREATMENT

6.4.1 OIIRR/Reliability of the Results

Weighted kappa test indicated that there was a substantial inter-examiner agreement for OIIRR (0.749, $p < 0.001$). There was also high intra-examiner agreement across the two scoring sessions by one of the investigators (Grant McIntyre) (0.938, $p < 0.001$).

6.4.2 OIIRR/Descriptive Statistics

The distribution of root resorption scores at the start of treatment (T0) and nine months later (T1) in each group and for the total sample is shown in Table 83 and Figures 36 and 37.

Table 83: Distribution of root resorption scores (0-4) at T0 and T1

Time	Group	Total Number	0		1		2		3		4	
			N	%	N	%	N	%	N	%	N	%
T0	0.018''	76	60	78.9%	13	17.1%	2	2.6%	1	1.3%	0	0.0%
	0.022''	76	61	80.3%	12	15.8%	2	2.6%	1	1.3%	0	0.0%
	Total	152	121	79.6%	25	16.4%	4	2.6%	2	1.3%	0	0.0%
T1	0.018''	76	14	18.4%	34	44.7%	21	27.6%	5	6.6%	2	2.6%
	0.022''	76	23	30.3%	33	43.4%	12	15.8%	6	7.9%	2	2.6%
	Total	152	37	24.3%	67	44.1%	33	21.7%	11	7.2%	4	2.6%

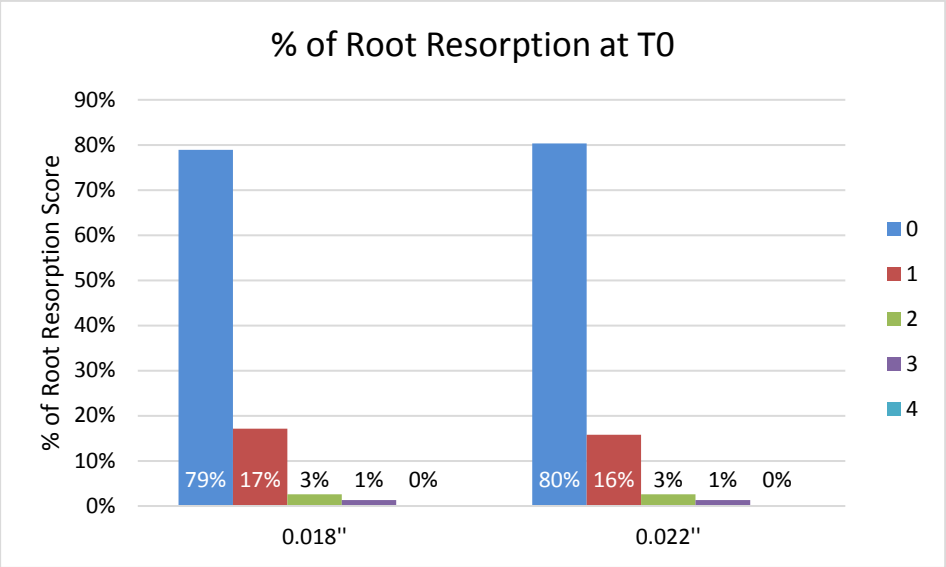

Figure 36: Distribution (%) of root resorption scores (0-4) in each group at T0

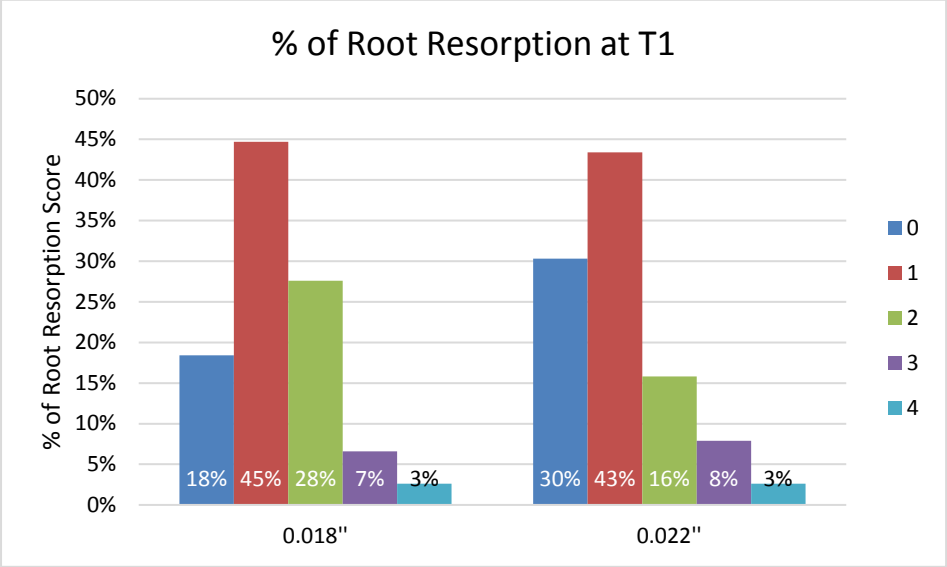

Figure 37: Distribution (%) of root resorption scores (0-4) in each group at T1

6.4.3 OIIRR/Comparison between 0.018'' and 0.022'' Groups

When Chi-square and Fisher's exact tests used to compare root morphology at T0, a statistically significant difference was found in the maxillary right central incisor where the 0.018'' group had a higher percentage of roots with apical pipette shape. No significant differences were found in other types of root morphology or in the maxillary left central incisor (Table 84).

Table 84: Chi-square for root morphology between the groups

Variable	Group	N	0	1	2	3	4	Pearson Chi-Square	df	p (Fisher's Exact Test)
UR1	**0.018''**	76	55 (72.4%)	8 (10.5%)	5 (6.6%)	2 (2.6%)	**6 (7.9%)**	12.482	4	**0.008***
	0.022''	76	63 (82.9%)	3 (3.9%)	10 (13.2%)	0 (0.0%)	**0 (0.0%)**			
UL1	**0.018''**	76	60 (78.9%)	6 (7.9%)	6 (7.9%)	3 (3.9%)	1 (1.3%)	1.711	4	0.849
	0.022''	76	58 (76.3%)	7 (9.2%)	9 (11.8%)	1 (1.3%)	1 (1.3%)			

*Significance level < 0.05

A Wilcoxon signed-rank test revealed highly statistically significant differences in the amount of root resorption between T0 and T1 in each appliance group and for the total sample as shown in Table 85.

Table 85: Related-samples Wilcoxon signed-rank test for root resorption between T0 and T1

Group	Time	N	Test Statistics	Standard Error	p
0.018’’	**T0**	76	1653.000	120.886	**0.000*****
	T1				
0.022’’	**T0**	76	1225.000	94.622	**0.000*****
	T1				
Total	**T0**	152	5671.000	302.037	**0.000*****
	T1				

*Significance level < 0.01

A Mann-Whitney U test revealed no significant differences in the amount of root resorption between 0.018’’ and 0.022’’ bracket groups at T0 and T1 (Table 86).

Table 86: Independent samples Mann-Whitney U test for root resorption at T0 and T1 between the groups

Variable	Group	N	Mean Rank	Test Statistics	Standard Error	p
T0	**0.018’’**	76	76.98	2851.500	190.174	0.848
	0.022’’	76	76.02			
T1	**0.018’’**	76	82.07	2465.000	255.919	0.098
	0.022’’	76	70.93			

*Significance level < 0.01

A Bonferroni correction was applied to control for family-wise error in root resorption data, because of a series of five non-parametric tests were carried out investigating different aspects of the data. Accordingly, the thresholds for declaring a result significant at the 0.05 and 0.01 levels were adjusted to 0.01 and 0.002, respectively.

CHAPTER 7: DISCUSSION

7.1 STUDY DESIGN

This study was a multicentre non-stratified prospective randomised clinical trial designed as a blinded, parallel group trial to compare the effectiveness of orthodontic treatment with the 0.018-inch and 0.022-inch slot pre-adjusted MBT bracket systems (3M-Unitek, Monrovia, California) in terms of the duration, quality, and biological side effects of treatment. This represents the most appropriate study design to find out if any clinical differences between the two appliance types exists.

7.2 HYPOTHESES

Restating the null hypotheses with acceptance or rejection will be listed first to confirm the general findings of the study.

7.2.1 Hypothesis 1:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *time required to complete orthodontic treatment*.

- The null hypothesis was accepted

7.2.2 Hypothesis 2:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *quality of orthodontic treatment outcome when measured using the ABO Cast-Radiograph Evaluation and PAR indices*.

- The null hypothesis was accepted

7.2.3 Hypothesis 3:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *incisor inclination near end of orthodontic treatment.*

- The null hypothesis was accepted

7.2.4 Hypothesis 4:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *first molar anchorage loss on completion of orthodontic treatment.*

- The null hypothesis was accepted

7.2.5 Hypothesis 5:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *patient experience with fixed appliances during orthodontic treatment.*

- The null hypothesis was accepted

7.2.6 Hypothesis 6:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *patient satisfaction with fixed appliance orthodontic treatment.*

- The null hypothesis was accepted

7.2.7 Hypothesis 7:

There is no significant difference between the 0.018-inch and 0.022-inch slot bracket systems in terms of *OIIRR after nine months of orthodontic treatment.*

- The null hypothesis was accepted

7.3 SAMPLE SIZE AND POWER OF THE STUDY

The sample size for the primary outcome was calculated to detect a difference of three months in the mean duration of orthodontic treatment, which was considered as a clinically significant difference. This was initially calculated according to the studies by Amditis and Smith (2000) and Eberting et al. (2001) (retrospective study and clinical report, respectively). However, the publication of a recent systematic review and meta-analysis which included 18 RCTs and 4 CCTs by Tsichlaki et al. (2016) that aimed to determine the mean duration and number of visits required for comprehensive fixed appliance orthodontic treatment enabled the sample size to be recalculated. It was also decided to calculate the sample size for the secondary objectives i.e. quality of occlusal outcomes using the ABO CR-EVAL and the biological sided effects (OIIRR).

7.3.1 Sample Size for the Primary Outcome

For total duration of orthodontic treatment, a power analysis utilising both a priori and post hoc components was used. The effect size for detecting a difference of three months was recalculated using a standard deviation of 5.3889 which was derived from the meta-analysis by Tsichlaki et al. (2016). The standard deviation was back-calculated from their published 95% confidence intervals. Based on a target alpha of 0.05, it was found that a sample size of 52 patients in each group was expected to have 80% power (a priori analysis) to detect a difference of three months and the inclusion of 153 participants (totally) achieved 92.8% power for this part of the study (post hoc analysis).

7.3.2 Sample Size for the Secondary Outcomes

An a priori power analysis was also carried out for the ABO CR-EVAL. The sample size was calculated to detect a difference of 5 points in the mean total ABO CR-EVAL score which was considered as a clinically significant difference (Detterline et al., 2010; Mislik et al., 2016) with the standard deviation was taken from Detterline et al. (2010).

A sample size of 73 patients in each group was expected to have 80% power to detect this difference and this was almost achieved in this part of the study. The effect size was calculated as a Cohen's D of 0.47 and target alpha was set at 0.05. Mislik et al. (2016) used the same criteria for sample size calculation but with a lower standard deviation (7) and found that a total sample size of 60 subjects could achieve a power of 80%, however using lower standard deviation was not justified. In both cases, the sample size of this study was sufficient.

For the root resorption scores, because this is a 5-point ordinal scale, normally authors do not report standard deviations. The standard deviation is necessary to calculate power using the G*Power software (Faul et al., 2009). It was possible to calculate a standard deviation of 0.84 from the data by Chen et al. (2015b). Using this estimate of variability, and selecting the ability to detect a difference of one scale point with an alpha level of 0.05 as a target, the calculated power of the current trial sample of two groups of 76 was 100% (to 6 decimal places).

It is worth noting that while some of the power analyses were carried out using post hoc power analysis, the estimates of effect size were not derived from the current results but from the pre-existing estimates of other studies. This was in order to determine how much power was achieved based on the attained sample size. This method is preferred when compared to the use of a conventional post hoc power analysis that depends on how large the effect that was observed from the same study to see whether enough number of people had been tested or not.

Based on the above results, this RCT was adequately powered and had the highest number of participants compared to the clinical trials reported in the meta-analysis by Tsichlaki et al. (2016).

7.4 RISK OF BIAS IN THE STUDY

In order to assess the study for a risk of bias that could overestimate or underestimate the true effect of a particular intervention, The Cochrane Handbook for Systematic Reviews of Interventions by Higgins and Green (2011) details the aspects that may introduce bias to a study and these should be taken into consideration as follows:

7.4.1 Selection Bias

Selection bias occurs if the intervention groups showed systematic differences in the baseline characteristics. This can be minimised by adequate randomisation including sequence generation and allocation concealment.

7.4.1.1 Random Sequence Generation

A simple randomisation sampling without stratification was performed to allocate participants to the appliance groups and to enhance sampling representation to the population using a computer generated random code (random number table). Stratifying the participants according to their demographic background was impractical due to the different variety of baseline variables that need to be stratified which in turn could dramatically increase the sample size. The precise restriction to a 10-number block within the randomisation ensured an equivalent number of participants in each group and this together with the use of a computer generated code can be deemed to have “low risk of bias”.

7.4.1.2 Allocation Concealment

Identical, opaque and sealed allocation envelopes containing a specific study ID number and the allocation group were prepared by one of the investigators who neither participated in treatment nor in the measurement of the completed data (Ahmed El-Angbawi). This allowed the principal investigator (Y.A.Y.) to receive only the list of

study participants which contained the study ID and the hospital number for each participant, whilst being blinded to allocation group.

The random sequence generation and allocation concealment should, therefore, result in two homogenous intervention groups with no systematic differences. This was confirmed in the comparisons between their baseline variables (Table 60). Therefore, the study was judged at a “low risk of selection bias”.

7.4.2 Performance Bias (Blinding of Participants and Personnel)

Performance bias refers to the systematic differences in the care provided between the interventions groups. Blinding (masking) the operators and participants to treatment groups could minimise the effect of performance bias. However, due to the nature of orthodontic treatment, it is usually impossible for orthodontic trials to be double blinded as the operators (particularly) and sometimes the patients know the type of treatment (Harrison, 2003). This agrees with different clinical trials using different appliance types (Pringle et al., 2009; Fleming et al., 2010; Borsos et al., 2012; Johansson and Lundström, 2012; Sandler et al., 2014; Hennessy et al., 2016). Therefore, both clinicians and participants were aware of the appliance group, however, a standardised treatment protocol was predetermined and no major variation from the protocol was detected. Moreover, the clinicians were in a position of “equipoise” and thus the performance was unlikely to be considerably biased by the lack of clinician blinding. Nevertheless, variation in clinicians’ experience with each system means this was considered to have a “moderate risk of performance bias”. Participant awareness of allocation had no influence on their treatment because they had no previous orthodontic experience and, hence, were unaware of the difference between the two appliances. Therefore, this could be deemed as a “low risk of performance bias”.

7.4.3 Detection Bias (Blinding of Outcome Assessment)

This refers to the systematic differences between groups in how outcomes are determined and it can be reduced by blinding (masking) the outcome assessors. The study records were anonymised and the principal investigator could only identify the participants using the study ID, hospital number, and the study model box number. All these did not reflect any information about the allocation group and the measurements were undertaken blindly. After completing the statistical analyses, the allocation table which was kept in a sealed envelope away from the clinical environment and from the investigator, was opened by the statistician to unmask the groups. Hence, this study was deemed to have a “low risk of detection bias”.

7.4.4 Attrition Bias (Incomplete Outcome Data)

Attrition bias refers to the systematic differences between groups in withdrawals from the study with incomplete outcome data. During the allocation, follow-up, and analysis stages of the trial the two groups showed a comparable number of dropout participants. Similarly, the total analysed number of participants included a small amount of missing data in some categories and they were evenly distributed between groups (Table 54). The record with the greatest missing data was the cephalometric radiographs (16.34% missing) with approximately double the number were missing for the 0.018’’ group when compared to the 0.022’’ group (17 versus 8 radiographs). These radiographs can be taken during the finishing stages of treatment (Isaacson et al., in 2015) and it was not possible to retake them at a later stage. However, the remaining categories either had no missing data or missing data ranging from 0.65%-7.84% which is relatively small number given the long treatment period and sample size. Statistical imputation was not used to replace the missing data, as this method could introduce bias. Therefore, the study could be considered to have a “low to moderate risk of attrition bias”.

7.4.5 Reporting Bias (Selective Reporting)

This represents the systematic differences between groups in reported and unreported findings. All the study objectives and outcomes were measured, analysed, and reported according to the published study protocol (El-Angbawi et al., 2014) and were clearly identified. The dropouts were reported and explained and, therefore, the study can be considered to have a “low risk of reporting bias”.

7.5 FLOW OF PARTICIPANTS

To allow for dropout during the treatment, 197 patients were enrolled in the study. The number allocated to the treatment groups was 187 participants as ten participants were excluded due to non attendance and other reasons. Seven participants were lost during the allocation stage where they either decided against proceeding with treatment or received the wrong appliance i.e. 0.022-inch slot brackets instead of 0.018-inch slot brackets. During the follow-up stage, 13 participants were lost without completing the treatment and without any further information i.e. either requested early appliance removal or transferred to another practice. In the final stage, 14 participants were excluded from data analysis because of very poor cooperation with treatment or protocol deviation.

The participants who were excluded during the allocation and follow-up stages (20 participants) accounted for 10.69% of the total allocated sample (187 particiapants), while the total excluded number of participants (34 participants) accounted for 18.18% of the total allocated sample. The 22 published clinical trials that were considered with high quality in the meta-analysis by Tsichlaki et al. (2016) showed either no reported dropouts or had a dropout rate up to 35.94% (Cattaneo et al., 2011). The latter study still showed adequate power which could be due to a large number of enrolled patients.

7.6 BASELINE DATA

7.6.1 Age

Patients were included in this clinical trial if they were aged 12 years and above. This was mainly for two reasons. Firstly, to ensure that maxillary anterior teeth had completed root formation to minimise the confounding effect of root development when assessing the severity of OIIRR. Secondly, to ensure the complete permanent dentition had erupted for fixed appliance orthodontic treatment and to minimise the possibility of two stages of treatment being required (e.g. removable and fixed appliances). The mean age in the study (19.05 years) was slightly higher than most of the clinical trials that have investigated treatment duration (Tsichlaki et al., 2016). This aligns with the increasing proportion of adult patients seeking orthodontic treatment over time as noted by Nattrass and Sandy (1995). The inclusion criteria differ from some clinical trials that have been restricted to an adolescent age group (Millett et al., 2000; Mandall et al., 2006b; Johansson and Lundström, 2012; Sebastian, 2012) or limited to an adult age group (Ma et al., 2008). The range of ages (12.05-58.46 years) included in this study was important as age was tested as one of the predictors that could influence treatment duration (discussed later in this chapter). In spite of this wide age rage, it did not significantly differ between the two appliance groups.

7.6.2 Gender

In both groups, the percentage of females was more than double that of males and there was no statistically significant difference in gender distribution between the two groups.

This higher percentage of females compared to males agrees with most of the clinical trials included in the meta-analysis for treatment duration (Tsichlaki et al., 2016) and it also agrees with other studies where females sought orthodontic treatment more frequently than males (O'Brien et al., 1996; Kerosuo et al., 2000; Harris and Glassell,

2011). This may reflect the higher level of concern expressed by females to correct their dental appeance when compared to males.

7.6.3 Type of Malocclusion

The current study included all types of malocclusions which were necessary to determine the influence of malocclusion on treatment duration, unlike some studies have assessed the duration of orthodontic treatment with only certain types of malocclusion (Popowich et al., 2005 and 2006). The overall sample showed higher percentages for both types of Class II and for Class III malocclusions compared with the prevalence of malocclusion in the Caucasian population (Mitchell et al., 2007). This could be explained because subjects with Class II or III malocclusions are usually more motivated to seek treatment when compared to those with Class I malocclusion and it may also be attributed to the IOTN criteria for selecting cases treated by the NHS secondary care centres. The distribution of malocclusion types in the current study is in agreement with the overall samples in the clinical trials by Fleming et al. (2009c) and Fleming et al. (2010), while the RCT by DiBiase et al. (2011) found that Class II division 1 was the highest among the malocclusion types in their study. Different distributions for malocclusion have been reported from different retrospective studies in the literature that have investigated the duration of orthodontic treatment. Some found a predominance of Class I (Amditis and Smith, 2000; Vu et al., 2008), while others have found that Class II malocclusion was in the majority (Vig et al., 1990; Beckwith et al., 1999; Pinskaya et al., 2004; Skidmore et al., 2006; Hamilton et al., 2008; Ang and Umesan, 2011). It should be noted that these retrospective studies depend on molar classification of malocclusion and did not use incisor classification as in this study.

In spite of the apparent variation in the distribution of Class II division 2 between the 0.018'' and 0.022'' groups, this was not found to be statistically significant difference.

7.6.4 Severity of Malocclusion

The severity of malocclusion was evaluated using the PAR index. The mean pre-treatment score value for the total sample and for both groups was slightly above 31 with no significant difference between groups. This mean pre-treatment PAR score was higher than that reported in some previously published studies (Robb et al., 1998; Firestone et al., 1999a; Teh et al., 2000; Turbill et al., 2001; Mascarenhas and Vig, 2002; Cassinelli et al., 2003; Haralabakis and Tsiliagkou, 2004) and was comparable to the results of other studies (McGuinness and McDonald, 1998; Popowich et al., 2006), while it was much lower than the pre-treatment PAR score reported by O'Brien et al. (1995). This may highlight the variation of malocclusion, the motivation of patients seeking treatment, treatment criteria and the referral policy in different regions.

7.6.5 Extracted and Impacted Teeth

The current sample revealed that orthodontic treatment for about three quarters of the cases included extractions and more than 90% of the cases had no impacted teeth. No statistically significant difference was found between the 0.018'' and 0.022'' groups in terms of the distribution of extracted or impacted teeth. The literature shows heterogeneity in reporting the percentage of cases treated with extractions. For example, it ranges from as low as 20% (Hamilton et al., 2008) to as high as 92% (Ang and Umesan, 2011) with some studies similar to the current findings, such as the study by Haralabakis and Tsiliagkou (2004) (70% of cases treated with extractions). This wide range of extraction rate in the literature agrees with Vig et al. (1990) who reported that the percentage of extractions in five different practices in the United States ranged from 25%-84%. The relatively high percentage of cases with extractions in the current sample may be explained by the relatively high mean pre-treatment PAR score. On the

other hand, the low percentage of cases with impacted teeth may represent their prevalence in the population.

It can be seen from the above description and comparison of the baseline variables that there were no statistically significant pre-treatment differences between the 0.018'' and 0.022'' groups, which means that the randomisation process was effective in producing homogenous groups before treatment. This could reduce the influence of confounding variables and ensure that the potential difference between the groups would be due to the type of intervention.

7.7 TREATMENT OUTCOMES

The primary objective of this clinical trial was to compare the duration of orthodontic treatment in months between the 0.018-inch and 0.022-inch slot bracket systems. The secondary objectives were to compare the quality of treatment and biological side effects of treatment between the two bracket systems.

7.7.1 Patient Compliance

Patient compliance during the trial was evaluated by measuring the number of failed appointments, emergency appointments, and broken appliances. Failed appointments are also termed cancelled, missed or broken appointments in different studies. These included all the cancelled appointment by patients or when they failed to attend and the appointment was rescheduled. Emergency appointments or extra/unscheduled appointments were counted if they were made due to breakages of appliances not when a breakage was observed at a scheduled appointment for activation or adjustment of the appliance. Broken appliances (appliance repair due to debond or deband) were calculated per loose or broken bracket, band, or tube. It is important to note that broken appliances did not include rebonded brackets due to incorrect positioning. These patient cooperation variables were also used in different retrospective studies that investigated

treatment duration (Shia, 1986; Fink and Smith, 1992; O'Brien et al., 1995; Beckwith et al., 1999; Amditis and Smith, 2000; Mascarenhas and Vig, 2002; Cassinelli et al., 2003; Popowich et al., 2005; Skidmore et al., 2006; Hamilton et al., 2008; Vu et al., 2008; Ang and Umesan, 2011).

Median numbers were used instead of means for these parameters in order to reflect numbers that are applicable in real life. Although the maximum number of failed appointments in both groups (0.018'' and 0.022'') was 16, the median number in both and for the total sample was one. Similarly, the median number of emergency appointments (one for the 0.018'' group and two for the 0.022'' group) and broken appliances (two for the 0.018'' group and three for the 0.022'' group) indicate that extreme cases did not affect the median value. The number of failed appointments was in agreement with that provided by Amditis and Smith (2000) (0.8 for 0.018'' and 1.0 for 0.022'' groups) and Popowich et al. (2005) (0.96), but it was less than that by other studies which ranged from 1.24 to 3.2 (Fink and Smith, 1992; Beckwith et al., 1999; Mascarenhas and Vig, 2002; Cassinelli et al., 2003). However, the variations between these studies were very limited.

Regarding emergency appointments, the medians of the current study were very slightly less than the mean[1] reported by Hamilton et al. (2008) (2.2). The median numbers of appliance breakages were in accordance with Popowich et al. (2005) (2.24) but slightly higher than the mean number of debonds for conventional brackets noted by Hamilton et al. (2008) (1.2), while these were less than the means reported by Beckwith et al. (1999), O'Brien et al. (1995), and Cassinelli et al. (2003) (ranged 3.8-7.5).

[1] Although this study used the median to reflect real life, this did not match most of other studies where they used means instead of median

Some of the compliance variables were difficult to compare with O'Brien et al. (1995), Skidmore et al. (2006), Vu et al. (2008) and Ang and Umesan (2011) because they provided their data as percentages or categories.

Some measures that were used for evaluating patient compliance, such as oral hygiene were not considered in this study as these might change throughout treatment and this may bias the results. The conclusion that can be drawn from this section is that the patients generally showed a comparable level of compliance when compared with patients in other published studies and there was a tendency to a reduced level of compliance in the 0.022'' group patients.

7.7.2 Number of Appointments

The number of scheduled appointments to activate or adjust the appliance were counted and compared between the 0.018'' and 0.022'' groups. Appointments used exclusively for oral hygiene instruction and unscheduled emergency appointments were not counted among the number of scheduled appointments.

The median numbers of appointments for the 0.018'' and 0.022'' groups were 16 and 17, respectively and the overall sample showed a median number of 16 appointments. This finding is in the middle of several studies that have reported data on the number of appointments. It was comparable to the means or range of appointment numbers provided by Alger (1988), Popowich et al. (2005 and 2006), Skidmore et al. (2006) (where 51% of their cases fell between 1-19 appointments), and Fleming et al. (2010). More interestingly, the meta-analysis by Tsichlaki et al. (2016) reported the mean number of appointments required during orthodontic treatment was 17.81 (95% confidence interval, 15.47, 20.15 visits). This was derived from five RCTs based on the data of 1211 participants and was close to the current findings. The data from other studies are not in agreement with the current results, where they found either higher

number of required appointments (Fink and Smith, 1992; Amditis and Smith, 2000; von Bremen and Pabcherz, 2002; Mascarenhas and Vig, 2002; Becker and Chaushu, 2003; Cassinelli et al., 2003; Haralabakis and Tsiliagkou, 2004; Vu et al., 2008; Ang and Umesan, 2011) or they have reported a slightly lower number of appointments (Hamilton et al., 2008; DiBiase et al., 2011; Johansson and Lundström, 2012; Jacobs et al., 2014).

This variation among studies in the number of appointments was mainly influenced by clinical decisions and appropriate to the needs of each case.

7.7.2.1 Comparison of the Number of Appointments

The non-significant difference in the number of appointments between the 0.018'' and 0.022'' groups can be explained by the minimum variation present between the two groups due to comparable pre-treatment characteristics. This finding disagreed with Amditis and Smith (2000) who reported that patients in the 0.018-inch slot bracket group required fewer appointments (18.9 ± 4.1) than the 0.022-inch slot bracket group (21.4 ± 3.6) and the difference in the means was statistically significant. This difference may be due to the earlier placement of the stainless steel working wires and fewer wire changes in the 0.018-inch slot group due to the use of the Roth prescription, which is likely to have resulted in confounding. The current study used a predetermined number and sequence of archwires for both groups according to the MBT philosophy to avoid this confounding and this may explain the non-significant difference between groups.

7.7.3 Appointment Intervals

The appointment interval was obtained by dividing the full duration of treatment by the total number of scheduled appointments. In this study, the appointment interval was 7.7 weeks and 7.8 weeks for the 0.018'' and 0.022'' groups, respectively. The current appointment intervals were in accordance with two UK RCTs where the interval was approximately six to eight weeks (Fleming et al., 2010; DiBiase et al., 2011). Few studies have reported appointment interval in their results, but it has been found that the current study showed an increased appointment interval when compared to other studies ranging from 5 weeks to 6.3 weeks (Alger, 1988; Popowich et al., 2005; Popowich et al., 2006; Hamilton et al., 2008). Vu et al. (2008) recommended frequent short visits with a short interval to minimise the duration of treatment. On the other hand, Alger (1988) suggested that increasing the appointment interval from four to six weeks would not affect treatment duration. However, these results were not confirmed with any level of statistical significance.

The longer appointment interval found in this study might reflect a high patient/clinician ratio in Tayside which could elongate the appointment schedules.

7.7.4 Duration of Treatment

Duration of orthodontic treatment was measured as the mean duration of full treatment in months from the date of bond-up fixed appliance to the date of debond. As there was no significant difference between the groups, the null hypothesis (hypothesis 1) was accepted. In order to describe the duration of treatment in detail, it was decided to measure the full duration of treatment as well as the duration of levelling and alignment, and working and finishing stages. "The levelling and alignment stage" was identified from the date of bonding the appliance to the date of ligating the working archwire (rectangular stainless steel wire). This was in accordance with Mandall et al. (2006b),

Scott et al. (2008b), Ong et al. (2011), and El-Angbawi (2013). The rest of the period from inserting the working archwire to the date of debond was considered as “the working and finishing stage”. This separation was implemented to identify if any variation occurred during a specific stage. However, it has been found that there was no clear cut-off point between these two stages because the clinician might go back to an earlier archwire and repeat the previous stage. Therefore, the full duration of treatment was more precise in measuring the duration of treatment and it was the main dependent variable of the primary objectives for this study.

The mean duration of full orthodontic treatment for the total sample within this clinical trial was 30.21 ± 10.98 months. When comparing the current finding with the 22 high quality clinical trials reported by Tsichlaki et al. (2016), it can be noticed that this trial was located in the upper limit for the duration of treatment, where only three clinical trials reported the duration of fixed appliance at 30 months or more (Miller et al., 1996; Xu et al., 2010; Borsos et al., 2012).

The long treatment duration in this study may be related to the appointment intervals and/or to the type and severity of malocclusion where there were relatively high numbers of participants with Class II division 1, Class II division 2, and Class III malocclusion when compared to the prevalence for the Caucasian population (Mitchell et al. 2007). Pre-treatment PAR scores were high in both groups (31.22 and 31.56) and these were higher than the pre-treatment PAR score for “difficult cases” provided by Cassinelli et al. (2003) (27.5 ± 9.3). This may reflect complex case-mix in hospital service at specialist practice. It has been stated that the higher the pre-treatment PAR scores and the greater percentage PAR score reduction, the longer the duration of treatment (Dyken et al., 2001).

A large number of retrospective studies have also reported the duration of orthodontic treatment with a wide variation of results. These range from as low as 15 months (Teh et al., 2000) to as high as 39.6 months (3.3 years) (Firestone et al., 1999a). The short duration of treatment found by Teh et al. (2000) in the General Dental Service in Scotland was explained due to the underestimation of treatment duration, low initial PAR scores, or termination of treatment before reaching the treatment goal. However, the study showed a large variation ranging from 2-41 months. Variations in other retrospective studies can be due to use of multi-phases of treatment, including among other reasons, cases with surgical treatment or only specific types of malocclusion (see section 2.1.1). These confounding factors were excluded in the present study.

7.7.4.1 Comparison of the Duration of Treatment

The 0.018'' group completed treatment about two months earlier than the 0.022'' group (29.26 ± 9.53 and 31.17 ± 12.26 months, respectively). This was reflected in the duration of the working and finishing stages, while the levelling and alignment stages were similar for both groups. However, neither the difference in the total duration of treatment nor the differences in the duration of the two stages of treatment were found to be statistically or clinically significant since the criteria were set so that a difference of three months would be considered as a clinically significant difference. The small amount of difference in the duration of treatment between the two groups may be associated with the small amount of difference in the degree of bracket-wire play in the working archwire with the 0.018-inch bracket (0.016 × 0.022-inch Stainless Steel) than that with the 0.022-inch brackets (0.019 × 0.025-inch Stainless Steel). As a result, the full expression of bracket prescription in the 0.018-inch slot bracket could be achieved slightly earlier than for 0.022-inch brackets and this may explain this minor difference.

Only two retrospective studies have directly investigated the duration of orthodontic treatment with these two bracket slot sizes and found statistically but not clinically significant shorter treatment with the 0.018-inch bracket group (Amditis and Smith, 2000; Detterline et al., 2010). The mean of treatment duration in the current study is positioned between these two studies. The reason for finding a statistically significant difference in the Amditis and Smith (2000) study but not in the current study may be due to the low variation present in that study as all cases were treated by a single clinician and hence a mean difference of 1.5 months was found to be statistically significant. Additionally, although the Amditis and Smith (2000) study used an equal number of archwires for both groups, it can be noticed that four rectangular archwires were used in the 0.018'' group while only two were used in the 0.022'' group in addition to the placement of the stainless steel working archwire 2.6 months earlier in the 0.018'' group. These factors could result in the 0.018'' bracket slot group achieving better control of tooth positions earlier in treatment. Whilst in the current study, an equal number of round and rectangular wires were used according to the protocol for both groups and this may have masked the difference between them. On the other hand, the significant difference in the Detterline et al. (2010) study could be related to the greater mean difference between groups (3.9 months). The mean duration for both groups in Detterline et al. (2010) (30.2 ± 12.9 for 0.018'' and 34.1 ± 14.4 months for 0.022'') were closer to our findings but both were much longer than that reported by Amditis and Smith (2000) (20.2 ± 3.1 months for 0.018'' and 21.7 ± 3.5 months for 0.022''). This may be explained due to the: (1) variation in patient cooperation (2) variation in technical skill and (3) greater number of clinicians undertaking treatment in both the current study and that by Detterline et al. (2010).

This study tried to overcome the limitations available in the above studies and other retrospective studies (Beckwith et al., 1999; Vu et al., 2008) by primarily investigating

the effect of bracket slot in a prospective RCT so avoiding selection bias. Although the difference was not significant in this study, interestingly it followed a similar trend to previous studies.

Regarding the stages of orthodontic treatment, the finding of the present study where the duration of the levelling and alignment stage was similar between the two bracket groups with different sequences of archwires agrees with two RCTs that could not find a statistically significant difference in the duration of the alignment stage with different archwire sequences using 0.018-inch slot brackets (Ong et al., 2011) and 0.022-inch slot brackets (Mandall et al., 2006b). Furthermore, three systematic reviews have been conducted to investigate the effectiveness of aligning archwires and could not find a significant influence of different archwires on the rate of tooth movement (Riley and Bearn, 2009; Wang et al., 2010; Jian et al., 2013). Therefore, it is unlikely that bracket slot size could have influenced the duration of levelling and alignment stage.

It was not possible to identify a study designed to investigate the duration of the working stage in order to compare it with the current findings.

7.7.4.2 Factors Influencing the Duration of Treatment

As this study investigated treatment duration, it was necessary to identify the variables that can influence duration. Therefore, 16 independent variables related to patient characteristics, patient cooperation, treatment modality, and treatment quality were considered to have a potential influence on treatment duration and were collected and measured throughout treatment (Table 66). These variables were analysed using a multiple linear regression analysis to identify the best model of significant predictors of treatment duration. Using a regression model to detect the predictors of treatment duration has been the subject of multiple retrospective studies. Some have investigated specific malocclusion groups (O'Brien et al., 1995; Stewart et al., 2001; Popowich et

al., 2005; Fleming et al., 2009a), whilst others similar to the current study were general (Vig et al., 1990; Fink and Smith, 1992; Robb et al., 1998; Beckwith et al., 1999; Teh et al., 2000; Turbill et al., 2001; Haralabakis and Tsiliagkou, 2004; Skidmore et al., 2006; Vu et al., 2008; Melo et al., 2013). Regarding the number of original variables entered in the regression analysis, some used a high number of variables, such as 31 variables (Beckwith et al., 1999) or 34 variables (Skidmore et al., 2006), while Haralabakis and Tsiliagkou (2004) included only six variables. The current study included an intermediate number of variables in order not to disturb the regression model with less important variables. No RCT has investigated the factors influencing the duration of orthodontic treatment, therefore this study can be considered as the first RCT investigating this subject.

It was decided to exclude time-related factors from the model, namely number of appointments and appointment interval as it was not a surprise that treatment duration could be predicted from these and there was a possibility that these strong predictors might mask potentially interesting lower level effects.

The regression model found that total treatment duration could be predicted significantly by five factors:

- ***Age at bonding***
- ***Class II division 2 malocclusion***
- ***Number of failed appointments***
- ***Number of emergency appointments***
- ***Whether patients had been treated by more than one clinician***

The predictive power of this model was able to explain about 33% of the variance in treatment duration (Table 67 and Figures 25 and 26).

By looking at the standardised coefficient of the significant predictors in the model (Tables 67), the sequence according to strength is as following: number of failed appointments, age at bonding, number of emergency appointments, Class II division 2, and number of clinicians.

The percentage of variability in treatment duration explained in the current study is illustrated with other studies in Table 87.

Table 87: Percentages of treatment duration variability explained by the current and other studies

Study	% Explained
O'Brien et al. (1995)	4.9%
Fleming et al. (2009a)	7.7%
Fink and Smith (1992)	24.9%
Teh et al. (2000)	29.2%
Stewart et al. (2001)	30.1%
Vig et al. (1990)	33.0 %
Current Study	**33.0 %**
Firestone et al. (1999a)	38.0%
Skidmore et al. (2006)	38.0%
Turbill et al. (2001)	41.0%
Taylor et al. (1996)	42.0% excluding number of appointments
Melo et al. (2013)	43.7%
Vu et al. (2008)	45.0%
Robb et al. (1998)	46.0%
Haralabakis and Tsiliagkou (2004)	46.3%
Beckwith et al. (1999)	53.6%
Popowich et al. (2005)	57.6%
Taylor et al. (1996)	77.0% including number of appointments

These differences among different investigations can be attributed to the variation in the inclusion criteria as some studies included multiple phases of treatment, surgical cases, optimally finished and prematurely terminated case etc. This heterogeneity made the comparison of the current study results with previous investigations difficult.

The next section will describe the significant predictors of treatment duration and their potential influences.

7.7.4.2.1 Age

Age at bonding showed a positive association with treatment duration in the regression model. With the series of current predictors, for each year increase in age, duration increases by 0.395 months.

The positive correlation of age with duration of treatment was in accordance with Shia (1986) and Becker and Chaushu (2003) and this can be attributed to more complex treatment with increasing age. Since all the patients included in the current study had permanent dentition and underwent a single treatment phase, it can be expected that younger patients would have shorter duration of treatment due to faster proliferation of the supporting tissues and easier tooth movement. The negative correlation of age with treatment duration in other studies was mainly attributed to the presence of mixed dentition, multiple treatment phases, or decreased cooperation for younger patients (Firestone et al., 1999a; Teh et al., 2000; Stewart et al., 2001; Turbill et al., 2001; Mascarenhas and Vig, 2002; von Bremen and Pancherz, 2002; Popowich et al., 2005; Ang and Umesan, 2011). We excluded participants in the mixed dentition, those with multi-phase treatment and those with poor cooperation to eliminate confounding arising from these variables. This study finding also disagreed with several studies that did not find a significant association between age and duration of treatment (Dyer et al., 1991; Robb et al., 1998; Fink and Smith, 1992; O'Brien et al., 1995; Beckwith et al., 1999; Skidmore et al., 2006; Vu et al., 2008; Parrish et al., 2011; Melo et al., 2013). Moreover, a systematic review by Mavreas and Athanasiou (2008) reported that age may not play a role in the duration of treatment when patients are in the permanent dentition and Fisher et al. (2010) stated that age is not the critical factor for duration of treatment but the presence or absence of deciduous teeth tends to be more important. These findings may result from the variability in age ranges included or the sample size when compared to the current study.

7.7.4.2.2 Class II Division 2 Malocclusion

This variable was “dummy coded” so that it revealed the effect of changing from Class I to Class II division 2 malocclusion. The model determined that this malocclusion group required an additional 4.741 months of treatment. Interestingly, this was similar to the finding of Vig et al. (1990) who reported that an additional 4.5 months were required for the completion of treatment if the starting malocclusion was Class II division 2. However, unlike the current study, Vig et al. (1990) depended on Angle’s classification not incisor classification. Taylor et al. (1996) mentioned that Class II division 2 was one of the factors that increased treatment duration.

Colella et al. (1994), Wenger et al. (1996), Skidmore et al. (2006), Hamilton et al. (2008), and Vu et al. (2008) also concluded that patients with a Class II molar relationship had an increased treatment time when compared to those with a Class I malocclusion. However, they neither mentioned the incisor classification nor separated between the two divisions of Class II malocclusion which in turn could be misleading.

As Class II division 2 treatment usually requires a large amount of incisor root movement, this may explain the association with longer treatment duration. The finding of Class II division 2 as a predictor for treatment duration agrees with Vig et al. (1990) and Taylor et al. (1996), and since the percentage of cases with Class II division 2 was greater in the 0.018’’ group (albeit non-statistically significant) (Figure 16) with a tendency of shorter treatment duration with the 0.018’’ group, this may suggest that in terms of the primary outcome (treatment duration), the study might be biased in favour of the 0.022’’ group which may mask a true effect i.e. that 0.018-inch slot brackets may in fact result in a reduced treatment time

7.7.4.2.3 Number of Failed Appointment

The number of cancelled or not attended appointments was also found to be associated with an increase in treatment duration. Each failed appointment can add 1.323 months of treatment time. This time was two weeks shorter than that for appointment interval, which was expected to be the time required for rebooking, however this may happen due to other patients cancellation so the clinicians were able to rebook with such a time period. This finding was similar to the finding by Beckwith et al. (1999) and Skidmore et al. (2006) where each missed appointment added 1.09 and 1.4 months to treatment time, respectively. More extremely, Vu et al. (2008) found that patients who missed fewer than two scheduled appointment completed treatment in 7.2 months quicker than those who missed two or more appointments. This study was also in agreement with Shia (1986) who reported broken appointments as one of the reasons for extended treatment duration, although he did not carry out statistical tests to prove this. Broken appointments, whether directly or indirectly (when calculated as a percentage of attended appointments) was also a significant predictor and showed a positive correlation with treatment duration in other studies (Fink and Smith, 1992; O'Brien et al., 1995; Robb et al., 1998; Ang and Umesan, 2011; Melo et al., 2013).

Even though it seems reasonable that failed appointments which reflect patient cooperation lead to increase in treatment duration, Popowich et al. (2005) could not prove this as a significant predictor in a sample of Class II patients. The nature of the Popowich et al. (2005) retrospective study, as well as selection bias when compared to the current study, may explain this difference.

7.7.4.2.4 Number of Emergency Appointments

Each emergency appointment significantly increased treatment duration by 0.950 months. This could also be considered as a logical finding as each extra appointment

may mean pausing treatment to repair the broken appliance. Only a few studies have included this variable in their regression model and they all agreed with the present findings (Skidmore et al., 2006; Vu et al., 2008; Ang and Umesan, 2011). Like failed appointments, this factor also reflects patient cooperation as it is usually scheduled due to appliance breakages/repair or trauma from the archwire that could happen from mishandling of the appliance by the patient.

7.7.4.2.5 Number of Clinicians

When more than one clinician contributed to the treatment of each patient, the duration increased by 4.071 months. This could be attributed to various reasons, including patients were treated in teaching centres where the treating clinicians move to other jobs at the end of their training leaving patients with longer treatment duration to be completed by other clinicians, which in turn compounds the appointment schedule and adds extra time for this group of patients. Additionally, the process of referral also takes time that consequently is added to the total duration of treatament. Only one study has directly investigated this correlation and found that if treatment was undertaken by more than one clinician the duration increased by an average of 8.43 months compared to treatment completed by a single clinician when standardised treatment had been provided with the same recall period (McGuinness and McDonald, 1998).

7.7.4.3 Factors <u>not</u> Influencing Duration of Treatment

It was surprising that some of the potentially influencing factors were not seen in the regression model. The possible reasons are listed below:

Gender: it may be assumed that although females may persevere with treatment to the maximum achievable result as they are generally more concerned with appearance when compared to males, they are usually more cooperative and hence this may mask the gender influence.

Class II division 1 and Class III malocclusions: these types of malocclusion may influence treatment if this was started early or was associated with growth modification appliances, while the current study avoided bias by excluding other treatment modalities. This may explain the non-significant results.

Severity of malocclusion (pre-treatment PAR): this could be because cases were recruited with an IOTN score of four or five according to the NHS Tayside Orthodontic Referral and Treatment Guideline which reduced the variation between cases in terms of their severity. Alternatively, variables such as patient cooperation may have elongated treatment duration and masked the effect of pre-treatment severity.

Impacted teeth: the low percentage of impacted teeth in both appliance groups and for the total sample (7.0%) may mask the actual influence of impacted teeth on treatment duration. Further prospective investigation with an adequate sample of impacted teeth may be required to investigate this relationship properly.

Extracted teeth: the present study included various extraction patterns which may also mask the influence of this factor. Nevertheless, the literature is not conclusive regarding the impact of extractions on treatment time.

Broken appliances: this variable could result in confounding along with other factors, such as the skill of the operator in bonding/banding teeth, the type of bonding/cement material, or the relation of debonds with certain types of malocclusion, which were not tested in this study. With an exception to the study by Skidmore et al. (2006), most of the studies in the literature have not investigated emergency appointments together with the number of appliance breakages as in the current study and hence from the results it can be concluded that the effect of the emergency appointments was greater than that of broken appliances because emergency appointments might be due to broken appliances

and other patient uncooperative behaviours. While broken appliances were counted per number of debonded brackets, therefore, having one or more than one debonded bracket at the same time could have the same consequences (booking one emergency appointment).

Intra-oral elastics: prescribing elastics might not have a substantial effect on treatment duration, but wear cooperation could influence this parameter. Consequently, it would be expected with the relatively good cooperation by patients in this clinical trial, wearing elastics was not significantly associated with an increase in the duration of treatment.

Bracket slot size (0.018'' vs. 0.022''): the effect of bracket slot size was the main objective of this clinical trial. Parallel to the finding of an insignificant difference in treatment duration between the two slot size groups, slot size was not a predictor of treatment duration for the total sample.

Archwire sequence: this can be explained as the clinicians aimed to maintain the study protocol without any major variations.

Quality of Occlusal Finish (%PAR and ABO CR-EVAL): it could be expected that better outcomes would require longer treatment duration as indicated by Dyken et al. (2001), but this was not found in the current study. On the other hand, studies that found an association between longer treatment duration and a deterioration in occlusal outcomes as measured with either the ABO CR-EVAL (Pinskaya et al., 2004; Knierim et al., 2006; Campbell et al., 2007; Wes Fleming et al., 2008) or PAR index (Al Yami et al., 1998; Turbill et al., 2001) linked this to the correlation with poor patient cooperation. This may confound the results.

Eventually, an equation for treatment duration could be derived from the regression analysis:

Regression Model Equation

Treatment Duration = 15.261 + 0.395*Age at bonding + 4.741 (if Class II division 2) + 1.323*Number of failed appointments + 0.950*Number of emergency appointments + 4.071 (if number of clinicians more than one)

7.7.5 Quality of Treatment/PAR Score

Since the results did not reveal significant differences between the appliance groups in terms of PAR index and ABO CR-EVAL, the null hypothesis (hypothesis 2) was accepted.

The criteria for categorising the PAR score results determine that at least 30% of PAR score reduction is required for a case to be judged as “improved” and in order to be considered as “greatly improved” a change of 22 points in PAR is required. Moreover, a high standard of orthodontic treatment can be reflected by a high mean percent of PAR reduction i.e. greater than 70% (Richmond et al., 1992b). In the present study, the amounts of PAR score change for the 0.018’’ and 0.022’’ groups were 23.85 points and 25.52 points, respectively. These and the mean percentage PAR score reduction for both groups [74.07% (0.018’’) and 77.13% (0.022’’)] revealed “great improvement” and a high standard of treatment.

This high percentage PAR score reduction could be explained by the high initial PAR score for both groups. Patients with high pre-treatment PAR scores have been found to demonstrate a greater reduction in the PAR score/improvement for their occlusion (O’Brien et al., 1995; McGuinness and McDonald, 1998; Firestone et al., 1999a; Teh et al., 2000; von Bremen and Pabcherz, 2002; Mascarenhas and Vig, 2002).

Table 88: The mean %PAR score reduction of the current study and other studies

Study	%PAR Reduction	Region
Teh et al. (2000)	59.2%	UK
Al Yami et al. (1998)	68.9%	Netherlands
Richmond et al. (1993a)	71.0% (cases treated with two-arch fixed appliances)	UK
Richmond (1993)	74.0%	UK
Fleming et al. (2010)	74.27% (conventional fixed appliances)	UK
O'Brien et al. (1993)	75.5% (cases treated with two-arch fixed appliances)	UK
Current Study	**75.57%**	**UK**
Birkeland et al. (1997)	76.7%	Norway
Mascarenhas and Vig (2002)	77.5% (cases treated in a graduate orthodontic clinic)	USA
Richmond and Andrews (1993)	77.8%	Norway
McGuinness and McDonald (1998)	79.95% (cases treated by more than one operator)	UK
González-Gil-de-Bernabé et al. (2014)	80.5%	Spain
Mascarenhas and Vig (2002)	80.9% (private practice orthodontists)	USA
Buchanan et al. (1996)	81.0% (pre-adjusted Edgewise group)	UK
Dyken et al. (2001)	81.7% (graduate student cases) 87.9% (Board-accepted cases)	USA
DiBiase et al. (2011)	82.92% (conventional fixed appliances)	UK
Kelly and Springate (1996)	89.0%	UK

The above are samples of studies that reported PAR scores for cases treated with dual arch conventional fixed appliances and predominately using the British weightings. The variability in percentage PAR score reduction could be attributed to the variation in the initial severity of malocclusion, sample size or to the differences in operator level of experience (specialists or postgraduate students).

7.7.5.1 Comparison of PAR Scores

It can be noted that the 0.022'' group has a slightly higher pre-treatment PAR score (0.34), lower post-treatment PAR score (1.33), and greater percentage PAR score reduction (3.06%). The initial similarity in pre-treatment malocclusion severity could account for the comparable degree of improvement between the two groups.

As with the present study, Amditis and Smith (2000) used the PAR scoring index to evaluate treatment outcome between the two bracket slot size systems. However, the study was retrospective and the authors did not provide any statistical comparison.

One retrospective study (Machibya et al., 2013) and two RCTs (Fleming et al., 2010; DiBiase et al., 2011) compared self-ligating and conventional brackets and found that the difference in percentage PAR score reduction was not significant between the two appliance types. In all these studies the initial PAR scores were 30-40 and there were adequate PAR score reductions. It can, therefore, be assumed from these studies and from the current RCT that variation in bracket slot size or bracket design has little or no effect on quality of treatment outcome, whereas the effect of initial severity of malocclusion would be greater in determining the amount of orthodontic improvement.

Even though the PAR index is widely used to measure the quality of treatment, it is not precise enough to distinguish between an excellent and a good final occlusion. This limitation is due to some missing aspects in the index, such as changes in facial profile and aesthetics, skeletal aspect, tooth angulation, spacing and crowding of buccal segments, functional occlusion, periodontal health, root resorption, root parallelism, psychosocial aspects, patient satisfaction and cooperation (Richmond et al., 1993b; O'Brien et al., 1995; McGuinness and McDonald, 1998; Dyken et al., 2001; Mascarenhas and Vig, 2002). Moreover, due to the different weighting systems for the PAR index, the comparison of international results is difficult (Fox and Chapple, 2004).

To overcome some of these limitations and in order to complement the treatment quality assessment between the appliance groups, this clinical trial also used the ABO CR-EVAL as it is more accurate than PAR index especially for detailed tooth position. Furthermore, the angulation of maxillary incisors, anchorage loss, root resorption, and psychosocial aspect in terms of patient perceptions were also measured.

7.7.6 Quality of Treatment/ABO CR-EVAL

The reason for including the American Board of Orthodontics Cast-Radiograph Evaluation (ABO CR-EVAL) in this study is because it offers an objective and stringent assessment of treatment outcomes, especially for detailed tooth position. When compared to the PAR index, it adds angulation, spacing and crowding of buccal segments, and root parallelism. Additionally, it uses the final models only to assess treatment outcomes, unlike the PAR index where both pre- and post-treatment models are required to measure improvement due to treatment. Due to the non-availability of a post-treatment dental panoramic radiograph, in accordance with the UK orthodontic radiography guidelines (Isaacson et al., 2008, updated by Isaacson et al., in 2015), this study only used the dental model analysis for the ABO CR-EVAL. This was in line with different investigations that have excluded the root angulation category (Abei et al., 2004; Cook et al., 2005; Costalos et al., 2005; Onyeaso and Begole, 2007; Hildebrand et al., 2008; Chaison et al., 2011; Song et al., 2013; El-Engebawy, 2015). However, it should be noted that some investigations have excluded two categories (Nett and Huang, 2005; Okunami et al., 2007; Wes Fleming et al., 2008).

Measurement of the ABO CR-EVAL was undertaken using a conventional (manual) method, as this has been found to be superior to the digital method (Okunami et al., 2007; Hildebrand et al., 2008; El-Engebawy, 2015).

The findings of this study showed that the mean total CR-EVAL scores for the 0.018'' and 0.022'' groups and for the total sample were slightly above 34 points. These scores were considered high and above the acceptable limit (less than 30 points lost) to pass the ABO phase III board examination and were above the total CR-EVAL score provided by investigations that excluded root angulation scores which ranged from 16.40-31.22. However, when considering the wide range of scores for these

investigations it could be concluded that these results might be attributed to different variables, such as the severity of pre-treatment malocclusion.

The ABO CR-EVAL scores did not seem to be associated with the PAR score results in the current study. Both the PAR and ABO CR-EVAL scores were comparable to those provided by Deguchi et al. (2005) who also found a non-significant correlation between the two indices. One explanation for this inconsistency between the ABO CR-EVAL and PAR indices was related to the superior ability of the CR-EVAL to assess finished cases in all three planes (first, second, and third order) precisely. On the other hand, the PAR index is considered superior for the evaluation of the improvement of malocclusion (Deguchi et al., 2005). The other potential explanations for the high ABO CR-EVAL score in this study are listed below.

The variation in the level of clinician experience (postgraduate students and orthodontic specialists) could account for adversely affecting the overall score in this study. This variation was partly in accordance with Abei et al. (2004) and Marques et al. (2012) who found that orthodontic specialists treated patients to better CR-EVAL scores than general dental practitioners, but this could not be confirmed by others who have not been able to prove that orthodontic specialists working in private orthodontic practice provide better orthodontic treatment outcomes (assessed by the ABO CR-EVAL) than postgraduate orthodontic clinics at university settings (Cook et al., 2005; Mislik et al., 2016).

An association has been found between longer treatment duration and poorer ABO CR-EVAL scores, which has been mainly attributed or associated with decreased patient cooperation due to burn-out (Pinskaya et al., 2004; Knierim et al., 2006; Campbell et al., 2007; Wes Fleming et al., 2008). In the current study, although no significant association was found between treatment duration and poorer ABO scores, it was noted

that both the mean values for treatment duration and the ABO CR-EVAL scores were relatively high for both appliance groups. Moreover, the longer treatment duration was significantly associated with the number of failed and emergency appointments which reflect patient cooperation. A non-significant association between treatment duration and ABO CR-EVAL scores was also indicated by Hsieh et al. (2005) and Vu et al. (2008).

The type of malocclusion could also play a role in influencing ABO results. Significantly better ABO CR-EVAL scores have been found with Class I malocclusion when compared with Class II malocclusion (Knierim et al., 2006; Vu et al., 2008). In this study, Class II malocclusion accounted 52% and 44% in the 0.018'' and 0.022'' groups, respectively, and may explain the high ABO scores.

The last possible reason for the ABO CR-EVAL scores may be because the current results represent a large pool of cases that have not been selected for quality assessment such as those usually presented for the ABO exam. This agrees with Yang-Powers et al. (2002) who found statistically significant better CR-EVAL scores for cases presented and passing the ABO exam when compared with those treated in a university setting. Interestingly, the ABO group cases had a mean overall CR-EVAL score of 33.88 ± 9.69 which is comparable to the results from the present study, whereas the score for the university group was 45.54 ± 18.33.

Alignment/rotation followed by occlusal contacts represented the poorest two components within the CR-EVAL scores in both appliance groups. This was comparable to the findings of other studies (Abei et al., 2004; Djeu et al., 2005; Farhadian et al., 2005; Kuncio et al., 2007; Wes Fleming et al., 2008; Mislik et al., 2016). Wes Fleming et al. (2008) reported that these two components were the first two important components that explained the variations in the total CR-EVAL score. Due to

the importance of alignment for orthodontic treatment, this component is heavily weighted in the CR-EVAL score and could account for double and even greater possible point deductions than the other components. This may explain the high score for the alignment. The occlusal contact scores, on the other hand, might reflect the inattention to achieving optimal inter-occlusal contacts by clinicians. Additionally, occlusal contacts of maxillary palatal cusps cannot be easily evaluated clinically unless multiple models are taken. Another possible explanation for the lower occlusal contact scores can be related to the time of taking the records which is on the day of appliance removal so that the teeth did not have enough time to be fully settled. The Nett and Huang (2005) study revealed that occlusal contact scores were significantly improved during the long-term post-retention period when compared to the “immediate” post-treatment scores.

With the exception of Cook et al. (2005), the current study agrees with all other published studies (especially those reviewed earlier in this thesis, section 2.2.2.2) in finding that the interproximal contact category resulted in the least score deduction. This may reflect the simplicity of identifying and treating spaces between teeth.

7.7.6.1 Comparison of ABO CR-EVAL Scores

Only the alignment/rotation and marginal ridges components were in favour of the 0.018’’ group, while the overjet, occlusal contacts, occlusal relationships, interproximal contacts, and the total ABO CR-EVAL scores were in favour of the 0.022’’ group. The differences between the groups were minor with a mean total CR-EVAL score difference of 0.22. Neither the total CR-EVAL nor any of the constituent components showed statistically or clinically significant differences.

The retrospective study by Detterline et al. (2010) found that after adjusting for the covariates, only the alignment/rotation and the total scores were statistically

significantly better for the 0.018-inch slot bracket group (26.3 ± 10.0) in comparison to the 0.022-inch slot bracket group (28.5 ± 11.3). The largest discrepancy for any component was 0.5 while in the present study this was 0.8 (marginal ridges). In both cases, these results did not show clinically relevant differences between the groups. Regarding the total score difference, this was 2.7 points in the Detterline et al. study, while it was 0.22 in the present study. Unlike this study, the clinicians in the study by Detterline et al. used a variety of bracket prescriptions and this variation in treatment philosophy could result in obfuscating the difference between the 0.018-inch and 0.022-inch slot bracket groups. This was avoided in the present study as variation in treatment between the groups was negligible because all the clinicians used identical brackets with MBT prescription and treatment strategies.

The comparison of the ABO CR-EVAL categories between the bracket slot size groups also revealed no significant differences within each category: “Low ABO”, “Medium ABO”, and “High ABO”. This result confirmed the above non-significant difference between the bracket slot size groups and consequently patients can be assured that treatment with either bracket slot size would be similarly effective. The current scores would have been higher if the root angulation component was included.

The ABO CR-EVAL is a powerful tool for assessing the quality of orthodontic treatment. However, some drawbacks were noted regarding the heavy weighting for scoring the posterior teeth compared to anterior teeth (Lieber et al., 2003; Chaison et al., 2011). Additionally, there are some aspects not covered by this index to be a comprehensive instrument for quality assessment, such as maxillary incisor angulation, facial and dental aesthetics, smile analysis, patient perception, and root resorption. Therefore, the ABO CR-EVAL should be used in conjunction with other orthodontic treatment outcome measures.

7.7.7 Quality of Treatment/Incisor Inclination

Torque expression is an important factor in determining treatment outcome in clinical orthodontics. The labiolingual inclination of the maxillary incisors plays a significant effect in profile smile attractiveness (Sarver and Ackerman, 2003; Cao et al., 2011; Ghaleb et al., 2011). On the other hand, the lower incisor position in relation to the surrounding soft and hard tissue has a leading role in orthodontic treatment (Corelius and Linder-Aronson, 1976). Accordingly, the maxillary and mandibular incisor inclinations were measured in this study to complement the ABO CR-EVAL (which measures buccolingual inclination for the posterior teeth but not the anterior teeth). As there was no significant difference in incisor inclination between the two appliance groups, the null hypothesis (hypothesis 3) was accepted.

In this study, maxillary and mandibular incisors showed proclination towards the end of treatment. In both 0.018'' and 0.022'' groups the U1-PP and L1-MP angles before and near end of treatment were consistent with the Eastman Standard for the UK Caucasian population (U1-PP = 109˚ ± 6˚ and L1-MP = 93˚ ± 6˚) (Mills, 1982).

7.7.7.1 Comparison of Incisor Inclination

Both types of appliances had caused a statistically significant amount of incisor proclination near end of treatment. The 0.018-inch slot bracket appliance proclined the maxillary and mandibular incisors by an average of 2.9˚ and 2.7˚, respectively. On the other hand, the 0.022-inch slot bracket appliance proclined the maxillary and mandibular incisors by an average of 1.5˚ and 1.4˚, respectively. Since these changes were small, they cannot be considered as clinically significant. Furthermore, the effect of bracket slot size was not statistically significant and both groups followed the same direction of change between the pre-treatment and near end of treatment stages i.e. there was no significant interaction between slot size and pre-treatment/near end of treatment.

The small difference in incisor inclination between the 0.018'' and 0.022'' groups could be related to the small amount of difference in the play between the working stainless steel wire and the 0.018-inch slot bracket (0.016 × 0.022-inch stainless steel, with an amount of play = 7.8˚) and that with the 0.022-inch slot bracket (0.019 × 0.025-inch stainless steel, with an amount of play = 9.5˚) (Johnson, 2013). Although, it has been found that the differences in the amount of play between archwire and bracket slot lead to variations in torque expression (Meling and Ødegaard; 1998; Sifakakis et al., 2013; Sifakakis et al., 2014; Arreghini et al., 2014; Papageorgiou et al., 2016), such a difference in play would be expected to be associated with a non-significant difference in the amount of incisor inclination between the two bracket slots.

The slots in the brackets used in the current study have been shown to be greater than the manufacturer's dimensions (but still within the DIN standards tolerance limit) with the exception of the depth of the 0.022-inch slot brackets which was significantly shallower (El-Angbawi, 2013). This was in line with different experimental studies that revealed variation in torque expression due to dimensional imprecision of brackets and archwires (Meling and Ødegaard; 1998; Joch et al., 2010; Arreghini et al., 2014; Lombardo et al., 2015). Therefore, this could also explain the non-significant difference between the two bracket slot sizes. Additionally, the largest wire size may not be fully engaged in the 0.022-inch slot bracket and hence this would reduce the expression of the prescription.

A similar trend of higher torque being delivered by the 0.018-inch slot brackets has been shown in different experimental studies (Sifakakis et al., 2013 and 2014; Papageorgiou et al., 2016). However, direct comparison with the present RCT was not possible due to the variations in study designs, variation in archwire sizes used and the

method of measurement, influence of other factors in practice, such as intra-oral ageing of fixed appliances and the influence of saliva among others.

The finding that pre-adjusted fixed appliances result in increased incisor inclination was in agreement with other investigations. However, they reported a greater amount of change when compared to the current study. Pandis et al. (2010) reported a greater amount of lower incisor proclination with both conventional and self-ligating 0.022-inch slot Roth prescription brackets (overall change for total sample: 92.5˚ to 96.9˚). The RCTs by Hennessy et al. (2016) showed that pre-adjusted MBT brackets with 0.022-inch slots resulted in 5.3˚proclination for the lower incisors (90.8˚ to 96.1˚). The differences between the above trials and the current trial may be attributed to differences in the archwire sequence, extraction rate, bracket slot type or techniques used in treatment. Nevertheless, the current results were closer to the Caucasian norms than the above investigations.

By adding this RCT to the literature, it can be postulated that bracket type (design, prescription or slot size) alone seems to have a little effect on torque expression (Pandis et al., 2006; Pandis et al., 2010; Mittal et al., 2015), whereas the combination of slot size and archwires is responsible for the expression of torque.

It is not easy to draw a conclusion from the above heterogeneous investigations regarding the influence of pre-adjusted bracket type or slot size on torque expression. This was partially because the above mentioned investigations that have considered bracket slots were laboratory-based with heterogeneity in study design. Moreover, the lack of standardisation in some investigations, such as using a wide variation of brackets, archwires, and ligation modes could also account for the different findings. However, there is a tendency that the 0.018-inch slot brackets may be superior in torque delivery compared to the 0.022-inch slot bracket systems. This could be due to the

ability to use a full-size rectangular archwire with 0.018-inch bracket slots with less torque play. However, this may have been masked in the current investigation by the variation in operator skills, difference in bracket dimensional precision between the groups, ligation methods, and other clinical variation. Furthermore, it should be acknowledged that the torque measurements were made during the finishing stages and not after completing treatment and thus further torque expression may have occurred before debonding the appliances.

Since the incisor angulations near end of treatment with both bracket slot groups were within the normal ranges, it could be stated that both bracket slot sizes can provide an equally effective amount of incisor torque.

7.7.8 Quality of Treatment/Anchorage Loss

This part of the current RCT aimed to compare the anchorage loss between two bracket slot size systems and as there was no significant difference between the groups, the null hypothesis (hypothesis 4) was supported. Anchorage loss between different bracket prescriptions (Rajesh et al., 2014) and between conventional and self-ligating brackets (Mezomo et al., 2011; De Almeida et al., 2013; Machibya et al., 2013; da Costa Monini et al., 2014; Juneja et al., 2015) have been investigated. However, no study has investigated the influence of bracket slot size on anchorage loss.

The sample for analysis for anchorage loss was selected where the treatment plan included therapeutic extraction of bilateral maxillary first or second premolars. Although these cases were selected assuming that all the extraction spaces were required for relieving crowding or overjet reduction (incisors retraction after achieving Class I canines), some confounding due to intentional space closure with mesial molar movement during treatment may bias the results for this part of the study. Almost all the studies that have evaluated anchorage loss have employed samples with bilateral

premolar extractions to assess the mesial displacement of the first molars. Unlike other studies using bilateral first premolar extractions (Ziegler and Ingervall, 1989; Rajcich and Sadowsky, 1997; Thiruvenkatachari et al., 2006; Yao et al., 2008; Mezomo et al., 2011; De Almeida et al., 2013; Machibya et al., 2013; da Costa Monini et al., 2014; Rajesh et al., 2014; Juneja et al., 2015), both bilateral first or bilateral second premolar extraction cases were selected in this study to increase the generalisability of the results. This was not expected to introduce confounding as there would be a non-significant difference in the amount of anchorage loss between cases with first or second premolar extractions (assessed from cephalometric radiographs or dental models) as reported by Geron et al. (2003). Moreover, Xu et al. (2010) and Sandler (2014) adopted different extraction patterns in their studies.

The medial ends of the third palatal rugae were selected as reference points in this study and they were easily located and showed an excellent level of reliability (both intra-examiner and inter-examiner agreement). This was in agreement with previous studies that found the medial ends are the most stable points and least affected by extractions and subsequent tooth movement (Lebret, 1962; Lebret, 1964; Van der Linden, 1978; Almeida et al., 1995; Bailey et al., 1996; Hoggan and Sadowsky, 2001; Christou and Kiliaridis, 2008; Jang et al., 2009; Chen et al., 2011; Shukla et al., 2011; Deepak et al., 2014). This is particularly true for the medial ends of the third palatal rugae which have been successfully used by previous studies for measuring tooth movement and maxillary first molar anchorage loss (Ziegler and Ingervall, 1989; Rajcich and Sadowsky, 1997; Geron et al., 2003; Rajesh et al., 2014).

Different techniques have been used for measuring anchorage loss (Ziegler and Ingervall, 1989; Rajcich and Sadowsky, 1997; Geron et al., 2003; Thiruvenkatachari et al., 2006; Yao et al., 2008; Thiruvenkatachari et al., 2009; De Almeida et al., 2013; da

Costa Monini et al., 2014; Rajesh et al., 2014; Sandler, 2014; Juneja et al., 2015), however, in this study, the use of 3D scanned models and measurement using proprietary software overcame the drawbacks with previous techniques, such as the use of ionising radiation, difficulty in the visualisation of landmarks, and magnification and superimposition errors. Moreover, the current technique is cheaper and less time consuming than the superimposition of 3D scanned models as geometric superimposition software is not required. Anchorage loss was measured separately for the right and left sides in this study. This is in agreement with Sandler (2014) who suggested separate measurements of the right and left molars for the assessment of the precise biomechanical effect of appliances on the position of the molar teeth rather than averaging both sides, which results in regression to the mean.

The amount of mean anchorage loss in both appliance groups varied from 3.30 mm to 3.86 mm and after excluding cases with anchorage devices it varied from 3.26 mm to 4.17 mm. This was slightly less than that found by Alhadlaq et al. (2016) when using a transpalatal arch with continuous arch mechanics (4.5 mm measured cephalometrically). However, anchorage loss was greater than that reported by Lee and Kim (2011) for both their TADs and conventional anchorage reinforcement groups where the conventional anchorage group wore headgear which could explain the reduced anchorage loss in that study. Similarly, Thiruvenkatachari et al. (2006) found no anchorage loss with TADs and a mean of 1.6 mm anchorage loss in the maxillary arch without TADs. Treatment with conventional bracket systems has shown mean anchorage loss ranging from 0.59 to 5.33 mm as reported in studies comparing conventional and self-ligating brackets (Mezomo et al., 2011; De Almeida et al., 2013; Machibya et al., 2013; da Costa Monini et al., 2014; Juneja et al., 2015). All the above studies used different methods for measuring anchorage loss with different reference points which could explain the heterogeneity in results. Rajesh et al. (2014) used the same measurement method

followed in this study to compare Roth and MBT brackets. In regard to the MBT appliance, they found the amount of anchorage loss for the right and left sides were 1.8 and 2.10 mm, respectively. This was approximately half the values in the present study and could be because anchorage loss was measured for the levelling and alignment stage, while in this study anchorage loss was measured at the completion of treatment. Therefore, it is likely that 50% of anchorage loss occurs during levelling and alignment and the remainder during the latter stages of treatment.

7.7.8.1 Comparison of Anchorage Loss

The 0.022-inch slot brackets showed 0.17 mm greater anchorage loss for the left side, while the 0.018-inch slot brackets showed 0.13 mm greater anchorage loss for the right side. These amounts were neither statistically significantly different nor of clinical importance. Excluding the influence of anchorage devices revealed that the 0.022-inch slot brackets were associated with greater anchorage loss for the left and right sides (0.5 mm and 0.31 mm, respectively) but again this did not reach the level of statistical significance. This trend may be due to the effect of higher forces generated by larger wire sizes with the 0.022-inch appliance on anchorage loss, but the difference was not sufficient to reach statistical significance.

In both the 0.018'' and 0.022'' groups with and without the presence of anchorage devices, it was clear (albeit non-significant) that anchorage loss was greater on the right side when compared to the left side. Rajesh et al. (2014) also found variation between the two sides, where this was greater on the left side. This may be due to occlusal variation which might retard the movement of one side compared to the other. The variability in anchorage loss between the right and left sides was also noted by Sandler (2014).

The above findings mean that the contribution of bracket slot size to anchorage loss is weak. Anchorage loss is likely to be influenced by other factors. This may include bracket prescription as Rajesh et al. (2014) found greater anchorage loss with Roth brackets (R: 2.9 mm, L: 3.10 mm) when compared to MBT brackets (R: 1.80 mm, L: 2.10 mm). This was attributed to the increased tip in the anterior segment for the Roth prescription compared to the MBT prescription. Furthermore, anchorage loss does not differ between conventional and self-ligating brackets (Mezomo et al., 2011; De Almeida et al., 2013; Machibya et al., 2013; da Costa Monini et al., 2014; Juneja et al., 2015) and this was confirmed by a systematic review and meta-analysis (Zhou et al., 2015). It can, therefore, be concluded from the above that the influence of bracket tip may be greater than the differences due to slot size or ligation method.

7.7.9 Quality of Treatment/Patient Perception of Fixed Appliance Orthodontic Treatment

Patient perception was assessed in terms of expectation, experience, and satisfaction with fixed appliance orthodontic treatment. Expectation was evaluated before the start of treatment, while experience after six months of treatment and satisfaction after completion of treatment. Three questionnaires namely: the Pre-treatment Questionnaire, the Smile-Better Questionnaire (Orthodontic Experience Questionnaire), and the Post-treatment Questionnaire were used in this study to achieve this goal. These questionnaires were validated during this trial in order to be applicable for patients wearing fixed appliances. A description of this validation study is available in Chapter 3 (section 3.1) and the study by Yassir et al. (2017a). Additionally, the IOTN AC was used before and after treatment as an adjunctive tool to assess patient need and satisfaction. The only drawback of this part of the study was that the validation process was carried out during the trial while most of the patients answered these questionnaires, therefore all the items that were merged after validation were analysed

separately in this analysis. Moreover, the newly added items related to tooth brushing (Pre- and Post-treatment Questionnaires) and smiling (Post-treatment Questionnaire) were not included in this analysis.

Since no study is available in the literature to compare perception of patients with 0.018-inch and 0.022-inch slot bracket appliances, the comparison of this study with other studies will only be undertaken for the general outcomes of the questionnaires.

7.7.9.1 Comparison of Patient Expectation of Fixed Appliance Orthodontic Treatment

This assessment can be considered as baseline data information to determine if any differences existed between patients in the two groups regarding their motivating influences and expectations toward orthodontic treatment.

No significant differences were found between patients in the two treatment groups in their expectations of fixed appliance orthodontic treatment, except for the item “To make it easier to bite into food” where double the number of patients selected score 2 in the 0.022’’ group. However, this statistically significant difference may not be of practical significance especially when patients in the 0.018’’ group who selected score 3 were also approximately double the number in the 0.022’’ group which would compensate any difference and indicate that this may be just a coincidence. The non-significant differences between the groups for the Pre-treatment Questionnaire items confirm the homogeneity of the sample and the effectiveness of the randomisation for this study.

In both groups, the main reasons for seeking treatment were to improve the following: appearance (especially dental appearance), smile aesthetics, self-concept and confidence, and occlusion of the upper and lower teeth especially for the anterior teeth, whilst getting on with people was not a reason for seeking treatment for the majority of

patients. Likewise, about half of the patients were not too interested to undertake orthodontic treatment to feel better about going out or to improve biting and chewing food.

The results revealed that patients are primarily concerned about anterior dental aesthetics and smiling and they might have thought that fixed appliances would have little effect on general facial aesthetics, occlusion of the posterior teeth and eating. It was also surprising to find that they did not consider their interaction with people as one of the major motivating factors for treatment. All these might reflect that they did not have problems in these aspects or they may have underestimated the effects of fixed appliance treatment and were particularly concerned about aesthetics more than functional or social aspects. The results of the current study are in agreement with the general conclusion of the patient perception section (Chapter 2, section 2.2.5.4). Moreover, the findings of the Pre-treatment Questionnaire are in line with several investigations that reported dental and facial aesthetics as the primary motive for seeking orthodontic treatment or as the main significant predictor of patient expectation of treatment and may be associated or followed by other domains such as oral function (e.g. eating) or social and emotional well-being aspects (Albino et al., 1981; McKiernan et al., 1992; Tuominen and Tuominen, 1994; Shue-Te Yeh et al., 2000; Bos et al., 2003; Kiyak, 2008; Wędrychowska-Szulc and Syryńska, 2010; Pabari et al., 2011; Anastasi and Spennato, 2014; Farishta, 2015; Feldens et al., 2015; Tang et al., 2015; Tuncer et al., 2015; van Wezel et al., 2015; Li et al., 2016). Nevertheless, the above aspects were generally found in most of the studies in the literature that have investigated expectation and motivation for orthodontic treatment.

Yi et al. (2016) used the Psychosocial Impact of Dental Aesthetics Questionnaire (PIDAQ) and found that the self-perceived psychological impacts of aesthetics and

malocclusion were significantly associated with the desire for orthodontic treatment. Although the aesthetic aspect was supported in current study, the social aspect, on the other hand, was less supported and this may be due to nature of the questionnaire used in that study which may direct the results more toward the psychosocial impacts.

The current study results are in agreement with the systematic review by Samsonyanová and Broukal (2014) which concluded that dissatisfaction with appearance was the main internal motivating factor for seeking orthodontic treatment. However, the other motivating factors found by that systematic review were related to external motivations which were out of the scope of the current questionnaires, such as dentist recommendation, parent and peer influences.

This randomised study aimed to provide a high quality evaluation of patient expectations and motivating factors for orthodontic treatment with different age groups to overcome the limitations that were indicated by two systematic reviews, such as deficiency of studies that investigated the motivating factors in orthodontic treatment and the need for questionnaire-based randomised studies to evaluate these factors with different age groups, heterogeneity, lack of standardisation of questionnaires and poor methodological quality (Samsonyanová and Broukal, 2014; Yao et al., 2016).

7.7.9.2 Comparison of Patient Experience with Fixed Appliance Orthodontic Treatment

The patients in the two groups did not show any significant differences in their experiences with the two bracket slot size appliances. Therefore, the null hypothesis (hypothesis 5) was accepted. Like other questionnaires in the current study, only the validated items were analysed. The Smiles-Better (Orthodontic Experience) Questionnaire was used to evaluate patient experience with fixed appliance orthodontic treatment and its impact on life after six months from the start of treatment. The impact

of fixed appliance in the literature was mainly measured using VAS scales or OHRQoL questionnaires (see section 2.2.5 and Table 13). The tool used in this study offered validated items for fixed appliances completed after a period of time which allowed an appropriate and realistic assessment of patient experience. This is because six months can be a reasonably representative period for the alignment stage experience and is less likely to be influenced by initial pain and discomfort that is generally experienced in the first week of treatment, patients after six months have accommodated to the fixed appliance and simultaneously it is not so far into treatment that they could lose motivation or would be waiting for the appliance to be removed, and finally it is a reasonable period for patients to notice the changes due treatment and be able to make appropriate judgements (El-Angbawi, 2013).

The validated items in the questionnaire can be categorised into four main sections: experience of wearing a brace, self-concept and interpersonal relations, pain and function, and hobbies.

7.7.9.2.1 Experience of Wearing a Brace

More than half of the patients (60.5% and 57.5% in the 0.018'' and 0.022'' groups, respectively) reported that wearing the appliances met their expectations. However, this still left a considerable percentage of patients who did not find fixed appliance as expected which in turn meant that more information should be provided in the patient information leaflet or patients need to be encouraged to read the leaflet more carefully. This was in agreement with the finding of the audit study using the Orthodontic Experience Questionnaire (Yassir et al., 2017b).

Although patients in the 0.022'' group reported a 10% higher percentage for extra appointments due to broken appliances (55.3% and 65.8% in the 0.018'' and 0.022'' groups, respectively), this difference did not reach statistical significance and it agrees

with the earlier finding in this study where the 0.022'' patients were found to have slightly higher median for emergency appointments. Once again, almost half of the participants in both groups were not bothered by these extra appointments.

More than 95% of the patients in both groups felt that their teeth were moving as expected due to wearing the appliances. This can be considered as a positive indicator reflecting patient awareness and engagement with treatment.

No significant difference was found between the groups in their ability to keep the appliances clean with more than half of the participants finding this a nuisance. This was in agreement with other studies where it has been reported that some participants found difficulty in cleaning and brushing the teeth and fixed appliances and maintaining good oral hygiene (Carter et al. 2015). de Souza et al. (2013) reported that 53.3% of their sample complained about the difficulty of using dental floss with fixed appliances. Furthermore, pain and discomfort were felt during tooth brushing and hence this negatively influenced oral hygiene (Marques et al., 2014; Rakhshan and Rakhshan, 2015). Therefore, it can be concluded that the similarity in the external design of both appliances used in this study may explain the non-significant difference between them, while the nuisance was probably due to their physical interference with the cleaning process as well as the discomfort felt during cleaning.

Similarly, the overall experience of wearing appliances was not significantly different between the 0.018'' and 0.022'' groups. Nevertheless, the results slightly favoured the 0.018-inch slot brackets (positive experience: 57.7% and 48.3%, negative experience: 5.8% and 10.3%, respectively). The encouraging aspect is that in both appliance groups the negative feedback was in the minority, while the majority of patients found treatment worthwhile and would recommend it to others.

7.7.9.2.2 Self-Concept and Interpersonal Relations

The majority of patients reported either no change or an improvement in their appearance due to treatment and the results slightly favoured the 0.022'' group. Although this contradicts the former percentage of overall experience between groups, both were not statistically significant. Similarly, the effect of any change in appearance did not alter relationships with family and friends or alternatively showed an improvement only for a few participants. This may explain the low percentage of negative feedback for the overall experience with both groups.

Although patients who reported an improvement in appearance were 40.3% in the 0.018'' group and 47.4% in the 0.022'' group, a feeling of embarrassment was not reported by 83.1% in the 0.018'' group and 86.7% in the 0.022'' group. This may reflect the popularity of wearing fixed appliances. This was in line with Brosens et al. (2014) who found that emotional well-being was better after one year of orthodontic treatment. It may also indicate that patient self-esteem has improved six months after the start of treatment which was in accordance with de Couto Nascimento et al. (2016). However in contrast with the current finding, Prado et al. (2016) found that fixed appliances resulted in a significant impact on aesthetics after six months of treatment although at the same time it caused significant improvement in psychosocial impact when evaluated with the PIDAQ Questionnaire. Implementing different tools to assess patient perception could account for this diversity in findings. In this study, the percentage of subjects who did not feel embarrassed due to wearing fixed appliances was 3.6% higher with the 0.022'' group and this reflected the slightly higher percentage of improvement in appearance in the 0.022'' group compared to the 0.018'' group.

Teasing generally showed no change or it decreased during treatment (probably due to an improvement in appearance and popularity of wearing braces) and it almost had no negative effect on schoolwork/work life or family and friends relationship.

In line with our study, Bernabé et al. (2008), Zhang et al. (2008), de Souza et al. (2013), Zheng et al. (2015) found that orthodontic appliances did not have a significant impact on social relations and contact. Liu et al. (2011a) reported an improvement in the social well-being during the treatment as detected with the OHQoL-UK questionnaire but not with the OHIP-14 questionnaire. The variation in these results could be attributed to the use of different instruments.

Our results regarding the emotional and social aspects were consistent with Zhang et al. (2007) who found that after six months from starting treatment with fixed orthodontic appliances, emotional well-being and social well-being were less compromised than expected by child patients before starting the treatment. An improvement in the emotional well-being after six months from the start of orthodontic treatment was also noted by Zhang et al. (2008).

7.7.9.2.3 Pain and Function

Most of the participants reported sore teeth, soreness in the mouth, and soreness from rubbing, however only a few rated the soreness as “a lot” while the majority rated it as “a little”. With the exception of soreness from rubbing, patients with the 0.018-inch slot brackets reported slightly higher levels of sore teeth and soreness in the mouth (a little and a lot collectively) than those with the 0.022-inch slot brackets and this was also noted with the influence of sore teeth and soreness in the mouth on schoolwork/work life where the results were also slightly in favour of the 0.022’’ group. This may be explained by the first aligning archwire in both groups being 0.016-inch super elastic nickel-titanium whereas the slot sizes were different leading to less play between the

archwire and bracket in the 0.018-inch slot brackets. Thus the greater forces could result in an increase in pain. However, all these differences were minor and did not reach the level of statistical significance. This high percentage of participants who felt pain from the appliances was in agreement with several studies in the literature that have evaluated pain perception with orthodontic treatment, although these studies predominantly investigated the period following appliance activation or archwire insertion and during early stages of treatment (Jones 1984; Brown and Moerenhout, 1991; Scheurer et al., 1996; Scott et al., 2008a; Krukemeyer et al. 2009; Tecco et al., 2009) and used different tools, such as VAS (Scott et al., 2008a, Pringle et al., 2009; Rakhshan and Rakhshan, 2015), OHRQoL questionnaires (Zhang et al., 2007; Zhang et al., 2008; Liu et al., 2011a; Mansor et al., 2012), or a survey (Krukemeyer et al., 2009). Rakhshan and Rakhshan (2015) interviewed patients 3-6 months after starting treatment and found that fixed appliances caused pain and discomfort that continued for more than four weeks after beginning treatment and interfered with tooth brushing and eating hard food. Using the same sample, Zhang et al. (2007 and 2008) reported a greater increase in oral symptoms after six months from the start of treatment compared to that before treatment but this was less than that experienced in the initial stages of treatment especially during the first week and first month.

Eating followed a similar pattern in both groups with similar percentages of patients who experienced a deterioration in eating (39.0% and 39.5%). This percentage for the effect of appliances on eating should not be neglected and it was slightly below but in agreement with the results by Yassir et al. (2017b). This may indicate that those patients underestimated the changes that would happen in diet and eating due to the impact of fixed appliances which is in agreement with Firestone et al. (1999b).

The difficulty with eating noted in the current study may be the result of pain reported by patients and this agrees with several published studies that found biting and chewing were common everyday activities affected due to the impact of fixed orthodontic appliances, however most of these studies have mainly investigated the initial stages of treatment (sometimes the first few days after appliance insertion) (Scheurer et al., 1996; Firestone et al., 1999b; Miller et al., 2007; Zhang et al., 2007; Bernabé et al., 2008; Chen et al., 2010b; Mansor et al., 2012; Abed Al Jawad et al., 2012; Johal et al., 2013; Kang and Kang, 2014; Marques et al., 2014; Carter et al., 2015; Rakhshan and Rakhshan, 2015). On the other hand, the Magalhães et al. (2014) study disagrees with our finding because it noticed that masticatory function and swallowing of hard food were only disrupted during the period of peak orthodontic pain, particularly 48 hours after archwire insertion. Neither mastication nor swallowing were disrupted by the orthodontic appliances after around three months of treatment.

Generally, it has been found from the aforementioned studies that the impact of fixed orthodontic appliances on dietary behaviour and eating decreased as treatment progressed. This may also be explained by the adptation of patients to the change in their dietary behaviour after a certain period of time. This could lead us to assume that the difficulty in eating which was experienced by about 39% of the participants in both groups in this study may not only be related to the difficulty in chewing and biting due to pain but other possible influences can also play a role in this. These include following the dietary instructions by avoiding eating hard, sticky or sugary food which might break the appliances or decalcify the teeth in addition to the social embarrassment with eating, for instance, the longer time taken to eat and difficulty in cleaning the appliances. All these might contribute to making eating more awkward and this explains the relatively high percentage of patients reporting difficulty in eating.

7.7.9.2.4 Hobbies

No significant differences were found between the patients in both groups for practicing hobbies and interests and most participants did not find a difference in practicing their activities with appliances.

7.7.9.3 Comparison of Patient Satisfaction with Fixed Appliance Orthodontic Treatment

Similarly to the validated Pre-treatment questionnaire, the Post-treatment Questionnaire items can be categorised into three main sections: dental and facial appearance, self-concept and interpersonal relations, and oral function.

Patients in both groups were satisfied with treatment outcomes with no significant differences being evident. However, the exception was that more patients in the 0.022'' group were dissatisfied about the occlusion of their posterior teeth. Although this may be coincidence spurious finding, it could be related to the difference in archwire sizes or the need for greater operator skill in finishing treatment using the 0.022 slot. Therefore, the null hypothesis (hypothesis 6) was accepted. In both groups, the main aspects that associated with patient satisfaction were the improvement in dental and facial aesthetics, improvement in self-concept and confidence, improved feelings about going out, occlusal improvement and to a lesser extent the improvement in chewing and biting. The only aspect resulting in dissatisfied patients was the non-improvement in getting on with people. However, the Pre-treatment Questionnaire identified this was not a reason for seeking treatment for the majority of patients, which could explain this finding. On the other hand, the attitude of patients might be changed toward some other items that were not reported as reasons for seeking orthodontic treatment i.e. those related to feeling better about going out and easiness of chewing and biting food, where in the Post-treatment Questionnaire these showed relatively high percentages of satisfaction.

This may reflect the increase in patient awareness about the ability of both appliances to improve aesthetics and function which is in agreement with Navabi et al. (2012).

The study finding was not in line with Al-Omiri and Abu Alhaija (2006) who found that satisfaction with appearance did not correlate with total satisfaction after orthodontic treatment, whereas satisfaction with eating and chewing was significantly correlated with total satisfaction. On the other hand, this study was consistent with Pabari et al. (2011) where orthodontic treatment was found to improve appearance, the perception of smile aesthetics, self-esteem, and self-confidence in adult patients. It was also in agreement with Johal et al. (2015) who found a significant improvement in patient self-esteem after treatment. In contrast, Kiyak (2008) in a review of the literature could not find any significant impact of orthodontic treatment on self-esteem.

Orthodontic treatment need before and after treatment was another aspect related to patient satisfaction evaluated in this study. Both slot size groups showed a significant improvement in the self-perception of aesthetics. This was in accordance with Feu et al. (2012) who revealed that orthodontic treatment with fixed appliances significantly improves aesthetic self-perception for adolescent patients. It was also consistent with the findings of the Post-treatment Questionnaire where patient satisfaction was noticeable in all dental and facial aesthetic items. Therefore, both bracket slot sizes were effective in delivering satisfactory treatment results from the patient perspective.

Concomitantly with the findings of the questionnaires, the IOTN scores revealed that no statistically significant differences were found between the 0.018’’ and 0.022’’ groups for both pre- and post-treatment which supports other results of the current study.

The finding of the current study was in line with the recent systematic review by Pachêco-Pereira et al. (2015) in terms of satisfaction with aesthetic improvement,

however other findings of that systematic review that related to patient personality or patient-operator interaction were not measured in the current study.

It should be noted that patient satisfaction was evaluated immediately at the end of treatment and this might bias the results as the impact of improvement produced by treatment was noticeable. Therefore, it would be important to investigate if a difference is present by evaluating long term satisfaction. This is because it has been reported that in the longer term, the benefit of orthodontic treatment reduces and the stability of treatment plays a greater role in predicting patient satisfaction regardless of the final results of treatment (Maia et al., 2010).

To summarise, bracket slot size did not contribute to any significant difference in patient perception. The results agree with the conclusion of the patient perception section in the review of literature chapter (Chapter 2, section 2.2.5.4). Dental aesthetics was the main factor associated with expectation and satisfaction with orthodontic treatment. During treatment, some pain and functional limitations were detected but they were also associated with positive features such as improvement in appearance with no negative impact on social life. It was difficult to compare the results of this study with the previously published studies as no other study has related bracket slot size with patient perception. Moreover, as pointed out by Zhou et al. (2014) in their systematic review, most of the studies that have investigated the impact of fixed appliances on quality of life were observational, focused on children, with no standardisation in the tools of assessment which were mostly not developed for fixed appliances (e.g. CPQ and OHIP). This study tried to overcome some of the above drawbacks by investigating patient perception during fixed appliance orthodontic treatment in an RCT using validated questionnaires for different age groups and focused on patient perspectives on treatment rather than their parents.

7.7.10 Biological Side Effects of Treatment/OIIRR

OIIRR is an undesirable consequence of orthodontic treatment and might be considered as the worst scenario that could happen and compromise the results of successful treatment. As there was no significant difference between the bracket slot size groups, the null hypothesis (hypothesis 7) was supported. External apical root resorption was evaluated in both groups in this study in terms of OIIRR of the maxillary central incisors using periapical radiographs before the start of treatment (T0) and after nine months from the start of treatment (T1). Since this part of the study was specifically measuring an irreversible biological side effect of orthodontic treatment, it was decided to take the worst score (either right or left incisor) for each patient in order to detect the greatest effect for each appliance.

7.7.10.1 Why Maxillary Central Incisors?

In this study, the OIIRR was measured for the maxillary central incisors because it has been reported that maxillary incisors are the most susceptible teeth for OIIRR (Remmington et al., 1989; Kaley and Philips, 1991; Brezniak and Wasserstein, 1993; Beck and Harris, 1994; Sameshima and Sinclair, 2001a; Pinskaya et al., 2004; Apajalahti and Peltola, 2007; Makedonas et al., 2013), with some studies finding that the central incisors were the most susceptible (Sharpe et al., 1987; Beck and Harris, 1994; Janson et al., 2000; Jung and Cho, 2011; Maués et al., 2015). Other studies, however, found the maxillary lateral incisors demonstrated more OIIRR than the central incisors (Sameshima and Sinclair, 2001a; Mohandesan et al., 2007; Nanekrungsan et al., 2012). The above findings may be attributed to the high load applied to incisors during orthodontic treatment due to the nature of their cylindrical small root surface (Jacobs et al., 2014).

Some studies evaluated one tooth, such as the left central incisor only (Mandall et al., 2006b), whereas others have evaluated both central and lateral incisors (Årtun et al., 2005; Årtun et al., 2009; Mohandesan et al., 2007). Evaluating one side would hide any adverse effect on the other side, while evaluating multiple teeth bilaterally might require more than two radiographic exposures. Therefore by assessing the right and left central incisors, this reduced the exposure to unnecessary radiation and avoided any undetected resorption on one side.

7.7.10.2 Why Periapical Radiographs?

A periapical radiograph with a long cone paralleling technique was used to evaluate OIIRR because it has been recommended as a conventional radiograph for detecting OIIRR (Sameshima and Asgarifar, 2001) and has been used successfully in RCTs to evaluate OIIRR (Mandall et al., 2006b; Scott et al., 2008b). Furthermore, it provides a more detailed view of the root structure with lower radiation, reduced image distortion, and fewer superimposition errors when compared with lateral cephalometric and panoramic radiographs (Brezniak and Wasserstein, 1993; Janson et al., 2000; Leach et al., 2001). Additionally, the use of CBCT could not be justified in this study because of the higher dose of radiation exposure (Makedonas et al., 2013).

7.7.10.3 Why 9 Months?

The nine month period was determined to be suitable for detecting OIIRR and identifying patients who might be at risk of severe root resorption throughout the full duration of treatment. This was in accordance with several investigations that reported OIIRR can be detected at least six months from start of treatment (Levander and Malmgren, 1988; Levander et al., 1998a; Årtun et al., 2005; Smale et al., 2005; Årtun et al., 2009; Ono et al., 2016). However it was not possible to collect all the radiographs exactly within the nine month period, hence about 20% of the radiographs were collected at about 10-12 months fron the start of treatment.

7.7.10.4 Evaluation of OIIRR

In this study, a qualitative method of scoring was used for quantification of OIIRR (Malmgren et al., 1982; Levander and Malmgren, 1988) which depends on the evaluation of morphological variation of root apex. Since periapical radiographs are not free from limitations for the detection of root resorption (Brezniak and Wasserstein, 1993; Brezniak and Wasserstein, 2002; Eraso et al., 2007; Dudic et al., 2008; Weltman et al., 2010), especially in their capability to detect defects in other root surfaces unless they are extensive (Brezniak and Wasserstein, 1993; Brezniak and Wasserstein, 2002), this explains the use of a scoring index that focuses primarily on apical OIIRR in this study. Though this method is subjective, it is less influenced by magnification or standardisation of the initial radiographs (Janson et al., 2000). Moreover, it showed high inter and intra-examiner agreement reliability (0.749 and 0.938, respectively). Assessing OIIRR qualitatively from periapical radiographs using the subjective scoring index was in accordance with different studies that assessed OIIRR with orthodontic treatment (Levander and Malmgren, 1988; Levander et al., 1998b; Janson et al., 2000; Harris et al., 2001; Marques et al., 2010; Motokawa et al., 2012; Picanço et al., 2013; Handem et al., 2016).

7.7.10.5 Comparison of OIIRR

Most other studies that have investigated the severity of OIIRR with orthodontic treatment differed from the current study either in the type of appliances, method of assessment, time of assessment, type of image used, or the teeth measured and this made the comparison with these studies difficult. Five studies have related the 0.018-inch and 0.022-inch slot brackets to OIIRR. Although Årtun et al. (2005) and Smale et al. (2005) divided their sample (which was the same in both studies) according to bracket slot size, they did not compare OIIRR between these groups. The third, fourth,

and fifth studies by Reukers et al. (1998b), Sameshima and Sinclair (2001b) and Årtun et al. (2009) will be discussed in the next paragraphs.

Both the 0.018'' and 0.022'' groups were similar in their pre-treatment scores. This ensured that any potential difference was credited to the influence of the appliances. An interesting pre-treatment finding was that about 20% of the cases in both groups showed varying degrees of root resorption (score 1, 2, and 3), predominantly score 1. This finding was in agreement with Newman et al. (1975) who found the prevalence of idiopathic root resorption was greater than they had expected. The only difference in the baseline data between appliance groups was for root morphology where the 0.018'' group had a significantly higher prevalence of roots with apical pipette shapes for the maxillary right central incisor.

At T1, some differences were detected between the groups especially for scores 0 and 2, where these scores favoured the 0.022'' group. However, unexpectedly this was not found to be statistically significant ($p = 0.098$) and it may reflect that the variation between the two groups has resulted in overlapping that masked this difference. The lower percentage of subjects in the 0.018'' group scoring 0 with a higher percentage scoring 2, while scores 1 and 4 were comparable, means that there is a higher probability of root resorption associated with the 0.018-inch slot bracket (however it was not statistically significant). This may be attributed to the reduced play between the initial archwires; 0.016-inch with the 0.018-inch bracket compared to 0.016-inch with the 0.022-inch bracket and this, in turn, could produce higher forces and hence greater root resorption and soreness in teeth and mouth. Kapila et al. (1990) found that the second order clearance between the 0.016-inch archwire and the 0.018-inch and 0.022-inch slot brackets was 0.32 and 0.95 degrees, respectively.

The higher percentage of roots with an apical pipette shape may also play a role in the higher probability of root resorption associated with the 0.018-inch slot bracket. When the data was checked, it was noticed that three patients with an apical pipette root had score 2 at T1, while the other three patients were distributed equally in the other groups (1, 3, and 4). Although these numbers were very small, they showed a higher possibility of root resorption with this morphological variation. The thin root apex associated with this morphology might make the root at greater risk to be resorbed. This agrees with other investigations that found roots with an apical pipette shape were the most susceptible to severe resorption (Levander and Malmgren, 1988; Levander et al., 1998a; Sameshima and Sinclair, 2001a).

The current results agree in part with the results of a randomised clinical trial that compared the severity of OIIRR between fully programmed edgewise appliances with Roth prescription (0.022-inch slot) and partially programmed edgewise appliances with Microloc brackets (0.018-inch slot) during full orthodontic treatment (Reukers et al., 1998b). The study revealed no significant differences in OIIRR between the two appliances, however that study used a different bracket prescription in each group and OIIRR was assessed at the end of treatment not after nine months from the start of treatment. The findings from the present study are also in agreement with Sameshima and Sinclair (2001b) and Årtun et al. (2009) who did not report a significant difference between the 0.018-inch and 0.022-inch slot bracket groups for root resorption, nevertheless, they did not present any of their data.

The non-significant differences in the severity of OIIRR between bracket slot sizes are in agreement with several investigations that have compared different types of brackets, such as conventional with self-ligating brackets (Blake et al., 1995; Scott et al., 2008b; Pandis et al., 2008; Fleming and Johal, 2010; Leite et al., 2012; Jacobs et al., 2014;

Chen et al., 2015b; Handem et al., 2016), fully with partially programmed brackets (Reukers et al., 1998b), the Bidimensional technique (0.018-inch slot for the incisors and 0.022-inch slot for the canines, premolars and molars) with the Roth straight-wire technique (Zawawi et al., 2014), different bracket prescriptions (Janson et al., 2000; Mavragani et al., 2000; Mohandesan et al., 2007; Zahed Zahedani et al., 2013), or different bracket slot sizes (Sameshima and Sinclair, 2001b; Årtun et al., 2009). Therefore, a conclusion could be drawn that bracket type and design has no influence on the severity of OIIRR, which is in agreement with the systematic review by Weltman et al. (2010). OIIRR might be related to other reasons such as individual susceptibility, type of orthodontic movement and forces applied.

From the above mentioned studies, we can compare our results with the conventional bracket results in the three studies that have used the same scoring index with periapical radiographs (Janson et al., 2000; Chen et al., 2015b; Handem et al., 2016). It is obvious form Table 89 (below) that the current study has the second highest percentage of teeth with no resorption (score 0). However, it shows the highest percentage with severe root resoption with score 4. Where score 3 and 4 are together considered as severe root resorption, the Chen et al. (2015b) study shows the highest percentage of severe root resorption. Nevertheless, these results should be interpreted with caution because the studies were retrospective and could be subject to various degrees of bias where they included maxillary and mandibular central and lateral incisors. Additionally, although the results of these studies were at the end of treatment, they excluded any case with root resorption at the beginning of treatment unlike the current study where about 20% of the cases presented with idiopathic minor root resorption and this may explain the relatively high percentage of root resorption in the current study after nine months. Marques et al. (2010) and Picanço et al. (2013) reported that the presence of root resorption prior to orthodontic treatment results in an increase in the prevalence of

severe root resorption during treatment. Other contributing factors to this difference with the current study could be related to the difference in archwire sequence and bracket prescription used. The Janson et al. (2000) results represented the total of three different bracket types, Chen et al. (2015b) did not mention the type of pre-adjusted conventional bracket, while Handem et al. (2016) used Roth bracket prescription.

Table 89: Comparison of the current study and other studies that have evaluated OIIRR

Study	% Root Resorption Score Due to Treatment				
	0	**1**	**2**	**3**	**4**
Janson et al. (2000)	2.3%	42.6%	53.4%	1.4%	0.4%
Chen et al. (2015b)	0.0%	55.7%	25.0%	17.1%	2.1%
Handem et al. (2016)	52.7%	34.2%	11.1%	1.9%	0.0%
Current Study	24.3%	44.1%	21.7%	7.2%	2.6%

Jacobs et al. (2014) found that the percentage of cases with severe root resorption (score 4) was 0.5% with 0.022-inch slot MBT brackets at the end of treatment, which was lower than our finding (2.6%) in both groups. Again, the exclusion of cases with root resoption at the start of treatment may explain this difference with the current study.

An interesting finding in the current study was related to the amount of OIIRR that both appliances produced after approximately nine months from treatment. Highly statistically significant amounts of OIIRR were associated with both the 0.018-inch and 0.022-inch slot brackets and for the total sample as well ($p < 0.001$). All studies in the literature that have investigated the impact of orthodontic tooth movement on apical root resorption have found an association between them with different treatment techniques and using different methods of assessment especially after six months and further from treatment. This was reported by all the review articles **(**Brezniak and Wasserstein, 1993; Brezniak and Wasserstein, 2002; Topkara et al., 2012; Feller et al., 2016) systematic reviews (Weltman et al., 2010; Tieu et al., 2014; Roscoe et al., 2015) and meta-analyses (Segal et al., 2004). However, the incidence of reported OIIRR varies

widely among investigations. This indicates that roots of teeth can easily be subject to resorption and special precautions should be taken to avoid unnecessary tooth movement or high forces during treatment.

Chen et al. (2015b) also found a significant amount of root resorption at the end of treatment with slightly harsher scores than ours. However, when they reported the linear measurements, the average root resorption with conventional brackets was 0.35 mm. Therefore, it could be predicted that the amount of root reorption in our study was generally at or below this value.

7.8 STRENGTHS OF THE STUDY

1. This is a novel study because it is the first prospective RCT that has investigated the effectiveness of full orthodontic treatment between the 0.018-inch and 0.022-inch slot conventional bracket systems.
2. The study was designed as an RCT which represents the gold standard design for comparing different interventions.
3. The study sample has the highest number of participants among other RCTs that have reported the duration of treatment with fixed appliances, particularly those with high quality that were included in the recent systematic review and meta-analysis by Tsichlaki et al. (2016).
4. The study has a very high power for the primary objective (92.8%) as well as for the secondary objectives (80.0% and 100%).
5. The study can be considered to have a low risk of bias overall.
6. The randomisation was adequate and this was reflected by the non-significant differences for the baseline variables between groups.
7. All the data collection, measurements, and statistical analyses were completed while the investigators were blinded (masked) to the allocation groups in order to reduce investigator bias.
8. The missing data were minimal and the patients who were excluded from the analysis were comparable between groups.
9. No major deviations were detected from the protocol of the study, which can influence treatment outcomes.
10. Robust data inspection and checking were undertaken for all the tests used in this study by a statistician.

11. Two indices were used to assess the quality of occlusal outcomes and were supplemented by the amount of anchorage loss and incisor inclination. This could be sufficient for the comprehensive evaluation of occlusal outcomes of treatment.
12. A novel method was developed for measuring anchorage loss using 3D scanned dental models with OrthoAnalyzer software. This can be considered as a convenient and accurate substitute to the photocopy technique of dental models.
13. This study was supported by three developmental studies. The first one validated the questionnaires used for patient perception. The second one included implementation of the validated questionnaire to assess the content of the British Orthodontic Society fixed appliance PIL. The third study provided information about the trend of UK specialists in terms of bracket slot sizes and prescriptions used.
14. A new set of three valid and reliable questionnaires for patient perception with fixed appliance orthodontic treatment were developed concurrently with this clinical trial and were used for this evaluation.
15. Treatment effectiveness in the appliance groups was evaluated according to the main aspects of treatment i.e. treatment duration, occlusal outcomes, patient perception, and the biological side effects of treatment. This provided a comprehensive comparison between the appliance groups.
16. The trial monitoring committee met frequently during the study to ensure that trial management and progress was in accordance with the Good Clinical Practice principles and to identify if any of the stopping rules needed to be applied.

7.9 LIMITATIONS OF THE STUDY

1. Some of the patients were lost to follow up after recruitment which did not allow them to be included in the study.
2. As in any RCT with orthodontic treatment, it was impossible to blind the clinicians and the patients for allocation groups.
3. Two patients requested appliance removal early. However, those were distributed equally between the groups.
4. One of the trial centres (Springfield Medical Centre) dropped out after recruiting three participants for the current study due to difficulty in managing recruitment and maintaining the required records for the study. Since this was at the beginning of recruitment, it did not impact on the study results. The other two centres were able to recruit a sufficient number of patients.
5. The study was undertaken in NHS teaching centres and in one area of the UK without including patients from different settings, such as private clinics. This could influence the generalisability of the study.
6. There is a possibility that the study was biased in favour of the 0.022'' group for treatment duration, incisor inclination and OIIRR due to higher proportion of cases with Class II division 2 in the 0.018'' group, although this difference in the proportion of cases was not statistically significant.
7. Root angulation measurement was not included in the ABO CR-EVAL scoring due to non availability of post-treatment panoramic radiographs.
8. Anchorage loss was measured for cases with bilateral premolar extractions without including the severity of crowding as an inclusion criterion. This could have reduced the sample size as the RCT was not designed to select cases for measuring anchorage loss. However, bias due to intentional space closure could occur. Additionally, although the technique used in this study for measuring anchorage loss

is novel, it is a two-dimensional measurement of three-dimensional subjects which may have introduced a small amount of error.

9. Validation of the questionnaires for patient perception was undertaken during the trial, so the analysis included only the valid items. Some of the answered non-valid items (deleted items) and the few additional items were not analysed.
10. Assessing OIIRR used a subjective index which could result in a degree of error.
11. About 20% of the participants had their periapical radiographs taken later than nine months of treatment (approximately between 10-12 months). However, due to the importance of this aspect of treatment and in order not to influence the results, the radiographs were collected within a period that agreed with most of the studies in the literature that have investigated OIIRR during treatment.
12. Archwire sequence was determined in the protocol, however, clinicians were also allowed to use different sizes according to patient need during treatment. Although this might reflect the “real world” clinical practice, it could disturb the standardisation of archwire sequence. However, no major deviations were detected.

Since the study limitations were relatively minor without any obvious influence on the primary or secondary outcomes of the trial, the study objectives were achieved with minimal impact from the above limitations.

CHAPTER 8: CONCLUSIONS AND RECOMMENDATIONS

8.1 CONCLUSIONS OF THE MAIN STUDY

This study was designed to compare the 0.018-inch and 0.022-inch slot orthodontic bracket systems, using the MBT prescription (Victory series, 3M-Unitek, Monrovia, USA) in terms of duration of treatment (primary objective), quality of treatment and biological side effects of treatment (secondary objectives). The study concluded:

1. There is no statistically significant difference in the duration of orthodontic treatment and number of appointments between the 0.018-inch and 0.022-inch slot MBT bracket systems.
2. Age at bonding, Class II division 2 malocclusion, number of failed appointments, number of emergency appointments, and number of clinicians explained 33.0% of the variation in orthodontic treatment duration.
3. There is no statistically significant difference in the quality of occlusal outcomes produced by the 0.018-inch or 0.022-inch slot MBT bracket systems when measured by the ABO CR-EVAL and PAR indices.
4. Both the 0.018-inch and 0.022-inch slot brackets deliver a comparable amount of maxillary and mandibular incisor torque.
5. Bracket slot size has no statistically significant influence on the amount of maxillary molar anchorage loss during orthodontic treatment.
6. There are no statistically significant differences in patient expectation, experience, and satisfaction with orthodontic treatment between the 0.018-inch and 0.022-inch slot brackets with both types of appliances resulting in a significant improvement in the self perception of aesthetics.

7. Both the 0.018-inch and 0.022-inch slot bracket systems are associated with a significant amount of maxillary central incisor root resorption at approximately nine months from the start of treatment. However, there is no statistically significant difference in the severity of root resorption between the two appliances.

8.2 MAIN CONCLUSIONS OF THE DEVELOPMENTAL STUDIES

1. Three content valid and reliable (internally consistent) questionnaires have been developed for the evaluation of patient expectations, experience, and the impact of treatment with fixed orthodontic appliances.
2. The survey study indicates that the vast majority of UK specialist orthodontists use conventional ligating MBT prescription brackets with the 0.022-inch slot size. However, this was not based on clinical evidence.

Finally, the 0.018-inch slot and 0.022-inch slot bracket appliances are comparable in their effectiveness of delivering orthodontic treatment and neither bracket slot was superior. Therefore, the suggestion of Rubin (2001), Peck (2001) and Kusy (2002) to adopt one slot size in order to standardise pre-adjusted fixed appliance orthodontic treatment biomechanics can be supported. This could be either of these slots or a new slot size, for example, 0.020-inch slot bracket.

8.3 CLINICAL IMPLICATIONS

In this study, a survey was conducted of UK orthodontists' preferences regarding bracket slots and the reason for using a specific bracket slot size and prescription (Chapter 3, section 3.2). The conclusion was that the vast majority of the respondents (98.7%) used the 0.022-inch slot bracket with MBT prescription. This was mainly because they perceived this combination to provide better treatment outcomes, or they were taught and trained using this combination. However, it is obvious from the current RCT that this perception was not based on solid clinical evidence and the evidence available from the current study revealed that both bracket slot sizes can be used with no significant differences in duration or outcome.

Adequate information should be provided for patients before commencing the treatment, such as information regarding the expected duration of treatment, particularly for cases with Class II division 2 malocclusion. This could enhance patient cooperation which was found to play a significant role in the duration of treatment. Moreover, if there is a possibility of undertaking treatment with more than one clinician, the increased duration of treatment should be considered and the patient informed.

Effort is required to adopt the ABO CR-EVAL in addition to PAR index in order to improve and standardise the occlusal outcomes of orthodontic treatment.

As significant root resorption occurs during orthodontic treatment, precautionary measures should be used to minimise this adverse effect (Brezniak and Wasserstein, 1993; Brezniak and Wasserstein, 2002; Segal et al., 2004; Lopatiene and Dumbravaite, 2008; Walker, 2010; Weltman et al., 2010; Topkara et al., 2012; Tieu et al., 2014; Feller et al., 2016). Prior to orthodontic treatment, the patient should be warned about the risk of root resorption. Additionally, taking a pre-treatment radiograph as a baseline record for later evaluation is necessary. Light intermittent forces with long intervals between

appointments are also recommended with another radiographic evaluation being preferable after 6-9 months from the start of treatment. If any abnormal root resorption or root morphology is identified during this period there might be a high risk for developing further root resorption later in treatment. Therefore, treatment should be paused for about 2-3 months. Whilst in cases of severe root resorption, the treatment plan can be modified or even terminated. Special consideration should be taken when a significant amount of tooth movement is planned over a long duration.

8.4 RECOMMENDATIONS FOR FUTURE STUDIES

1. Developing a new system of bracket slot size, for example, 0.020-inch slot bracket and evaluating its effectiveness compared to the 0.018-inch and 0.022-inch slot bracket systems.
2. Comparison of the effectiveness of orthodontic treatment between the 0.018-inch and 0.022-inch slot bracket systems in different treatment settings and geographical regions.
3. Evaluation of operators influence, perception, and experience with the 0.018-inch and 0.022-inch slot bracket systems during orthodontic treatment.
4. Comparison of anchorage loss with different bracket slot sizes for cases with type “A” anchorage (high demand for anchorage).
5. Assessment of OIIRR associated with orthodontic treatment starting with light force archwires (during and after orthodontic treatment).

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APPENDICES

Appendix 1: Patient Information Sheet

Is the 0.018-inch slot or the 0.022-inch slot bracket system more effective in orthodontic treatment?

Patient Information Sheet

We invite you to participate in a research project. We believe it to be of potential importance. However, before you decide whether or not you wish to participate, we need to be sure that you understand firstly why we are doing it, and secondly what it would involve if you agreed. We are therefore providing you with the following information. Read it carefully and be sure to ask any questions you have, and, if you want, discuss it with outsiders. We will do our best to explain and to provide any further information you may ask for now or later. You do not have to make an immediate decision.

THE BACKGROUND TO THE STUDY

- What is the research about?
  Investigating two types of orthodontic brace currently used in NHS Tayside.

- Why is the research being done?
  We do not know which type is better.

- Who is sponsoring it, and are they paying the researcher or his/her department to do the research?
  University of Dundee. None of the researchers is being paid to do this research.

- Why have I been chosen as a possible participant in the research?
  You or your child's orthodontic treatment could be carried out using either orthodontic brace

- How many other people have been asked to consider participating?
  216

WHAT DOES THE STUDY ENTAIL?

- Will I have to come back to the clinic more often or remain in hospital longer than would normally be the case?
  No

- What will I be asked to do at each visit?
  At each routine visit nothing additional to the usual adjustment of the braces, except for at the start and end of treatment when you will be asked to give a score to your smile using a simple questionnaire in the clinic.

- How long will my participation in the study last?
  Until completion of your orthodontic treatment

- What procedures will I be asked to submit to and what will they be like?
    1. *You will have normal brace treatment with one of the two types of brace currently used in NHS Tayside, which includes having moulds of your teeth and photographs and x-rays taken.*
    2. *Two additional small close-up x-rays for your upper front teeth will be taken at the start of treatment and after 9 months as part of this research. These have been approved by the Clinical Radiologist at Dundee Dental Hospital and by the Medical Physics Department.*

- What treatment will I get if I do take part?
  The same high quality of orthodontic treatment we provide on a routine basis at Dundee Dental Hospital, Perth Royal Infirmary & Springfield Medical Centre.

- Will this be different from the treatment I would get otherwise?
  No

- Will the decisions about my treatment be made by my usual doctor or by someone else?
  Yes, by the Consultant or his/her deputy

- What are the names and amounts of drugs which I will be given (if any) and by what route?
  No drugs are involved in this study.

- Will all patients receive active treatment, or will some receive dummy medication? Is so, what is the chance that I would receive dummy medication?
  All patients will receive active treatment

- Were I to feel severe discomfort or pain during the study, would I be able to take any relief medication?
  Yes, as recommended by the clinician

- Is there any chance that the proposed research will be of benefit to me personally, or to future patients with the same condition?
  We hope to help orthodontists choose the best brace type for future patients.

- Are there any factors, which would exclude me from participating, like pre-existing illness, the possibility of becoming pregnant or other drugs being taken?
  Yes, if you fall into one of the following categories:
  You have undergone previous orthodontic treatment.
  You are less than 12 years old at the beginning of the study.
  You have a cleft lip or palate, multiple missing teeth or have special needs.
  You are having jaw surgery as part of their treatment.
  If you suffer from hypothyrodism, hypopituitarism or hyperpitutarism.

- Were the new treatment to be of benefit to me, could I continue to take it after the trial?
  Your full treatment will be covered by the study.

WHAT ARE THE DISCOMFORTS, RISKS AND SIDE EFFECTS?

- Will there be any discomforts, such as additional needle pricks or biopsies, or pain, and if so, how much and for how long?
  No

- Are there likely to be side effects from what will be done to me in the research, and if so what are they?

None

- Who should I contact if I am worried about any side effects that I experience?
  Chief investigator: Prof David Bearn.
  Professor of Orthodontics, University of Dundee Dental School Park Place Dundee DD1 4HN
  Tel: 01382 635978, e: d.bearn@dundee.ac.uk.

- Is there any chance of anything going wrong, and if so, what are the risks compared to everyday activities?
  Only the same risks as undergoing brace treatment not as part of the research.

- Would I be withdrawn from the study if my condition became worse or if any extra risks came to light during the course of it?
  Yes, and we will continue your care.

- Are there any activities I should refrain from during and in the period following the research and for how long, eg, blood donations, taking other medication, exposure to sunlight, driving, taking part in other studies?
  Only those that all patients undergoing brace treatment should avoid.

  If you agree to participate in this study, you will be entered into the trial register (held on computer) and will be allocated the next available study number. The study number will correspond with a numbered sealed envelope, which will be opened when your treatment is about to begin. Each envelope will contain a sheet with the details regarding the type of brace that will be used for your orthodontic treatment and will have been allocated in advance using a computerised random number generator.

WHAT WILL HAPPEN TO THE INFORMATION COLLECTED IN THE STUDY?

- How will my confidentiality be protected, ie, who will have access to the records generated and what steps will be taken to ensure that they will only be seen by those authorised to see them?
  Only the named researchers involved in this study will have access to the data that will be recorded.

- Will my dentist be told that I am taking part in this study, and the results of my participation?
  We will inform your dentist that you are participating in the study.

- If any illness of which I am presently unaware is found as a result of the study, will I be told and receive any treatment for it?
  Yes.

- If the research may result in me or my relatives being made aware for the first time of our susceptibility to an illness, what arrangements have been made for counselling?
  This will not happen in this study.

- Will I be informed of the results of the study?
  No – this study is not being funded by any outside body. Therefore we believe the resources involved in contacting individual patients should be used for continuing patient care in dealing with our lengthy waiting list.

WHAT ARE MY RIGHTS?

- How can I obtain more information if I wish?

Contact one of the researchers involved in this study – we would be delighted to discuss any aspect with you

- Can I discuss the study with friends and relatives, or my GP before deciding whether to take part?
  Yes

- Can I refuse to take part or change my mind later even if I agree to take part now?
  You can refuse to take part, although your orthodontic treatment will involve one of the two orthodontic braces we are investigating in this study anyway. Once treatment is underway, it would not be appropriate to remove your orthodontic brace unless there are clinical reasons for doing so.

- If I do refuse to take part or change my mind later, will I still get the treatment my usual doctor thinks is right for me?
  If you agree to participate, your orthodontic treatment will be identical to that if you refused to take part, as we treat all our patients to high and exacting clinical standards.

- If something went wrong, how and from whom would I obtain compensation?
  As an NHS patient being treated in NHS Tayside, you should initially address any complaint to the Consultant in charge of your orthodontic treatment.
  If you believe you have been harmed in any way by taking part in this study. You have the right to pursue a complaint and seek any resulting compensation through the University of Dundee who are acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the ususal NHS process. To do so you can submit a written complaint to the Patient Liaison Manager, Complaints Office, Ninewells Hospital (Freephone 0800 027 5507). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Tayside but you may have to pay your legal costs.

- Will I get travelling expenses or other payment?
  No.

Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your future medical care or your relationship with medical staff looking after you.

The Tayside Committee on Medical Research Ethics, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from NHS Tayside and the Regulatory Authorities.

Thank you for reading this Information Sheet and considering your participation in this study

Appendix 2: Consent Form

CONSENT FORM

Is the 0.018-inch or the 0.022-inch bracket slot system more effective in orthodontic treatment?

Name of researcher:

Please Initial Box

1. I confirm that I have read and understood the information sheet dated 1/10/2009 (version 1.1) for the above study. I have had the opportunity to consider the consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at anytime without giving any reason, without any medical care or legal rights affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Dundee Dental School and Hospital and Tayside NHS where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records. ☐

4. I agree for my dentist to be informed of my participation in this study. ☐

5. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of parent/guardian *(if appropriate)*	Date	Signature
Name of person taking consent	Date	Signature

When complete, 1 for the participant; 1 for research site file; 1 (original) to be kept in medical notes

Appendix 3: Old version of the Pre-treatment Questionnaire

Treatment Questionnaire (Before)

These are some of the reasons why people want nicer teeth.
Please draw a ring round **one** of the numbers on each line.

	Not a reason			**Very much a reason**
To make my smile nicer	**1**	**2**	**3**	**4**
To help me chew food better	**1**	**2**	**3**	**4**
To make my family happy	**1**	**2**	**3**	**4**
To help me with my school work	**1**	**2**	**3**	**4**
To make my teeth look nicer	**1**	**2**	**3**	**4**
To help my breathing	**1**	**2**	**3**	**4**
To feel more confident	**1**	**2**	**3**	**4**
To help my top and bottom teeth fit together	**1**	**2**	**3**	**4**
To help me speak more clearly	**1**	**2**	**3**	**4**
To make my face look better	**1**	**2**	**3**	**4**
To make me feel better about myself	**1**	**2**	**3**	**4**
To keep my gums healthy	**1**	**2**	**3**	**4**
To make me healthier	**1**	**2**	**3**	**4**
To keep me from losing teeth in the future	**1**	**2**	**3**	**4**
To help me make friends	**1**	**2**	**3**	**4**
To keep my jaw joints healthy	**1**	**2**	**3**	**4**
To help my front teeth fit together	**1**	**2**	**3**	**4**
To make me look better	**1**	**2**	**3**	**4**
To make me feel better about going out	**1**	**2**	**3**	**4**
To help keep my jaw joint from clicking	**1**	**2**	**3**	**4**
To help my back teeth fit together	**1**	**2**	**3**	**4**
To make it easier to get on with people	**1**	**2**	**3**	**4**
To make it easier to bite into food	**1**	**2**	**3**	**4**

Please tell us on the other side of the page if there are any other reasons why you want nicer teeth

Appendix 4: Old version of the Smiles-Better Questionnaire

6 months from start of treatment

Smiles Better

A few questions about you and your brace

A Few Questions About You And Your Brace

We would like to know how you feel about wearing your brace. By answering these questions, YOU can help to make wearing a brace better for people in the future.

Please circle the answer, which is nearest to how you feel, like this:

If you think wearing a brace has improved your smile put a ring around *improved*
or
How often do you play sport Not at all A little A lot

*Please tell us about how you feel **NOW**, not about when your brace was new.*

---

1. How much have the following things changed because of wearing your brace?

Speech	Improved	Same	Slightly worse	Much worse
Eating	Improved	Same	Slightly worse	Much worse
Drinking	Improved	Same	Slightly worse	Much worse
Sleeping	Improved	Same	Slightly worse	Much worse
Appearance	Improved	Same	Slightly worse	Much worse
I am teased	Less	Same	Slightly more	Much more

2. Now you are wearing a brace, how have the following affected you?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean is a nuisance	Not at all	A little	A lot

We would like to know if wearing a brace can affect other things in your life.

SCHOOLWORK

3a. How have the following things associated with wearing a brace affected your schoolwork?

For example, if you think your schoolwork is better you would put a ring around **improved**

How have any changes in your speech affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in your eating affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in how you drink affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in your sleep patterns affected your schoolwork ?	Improved	Same	Worse	Much Worse
How have any changes in your appearance affected your schoolwork ?	Improved	Same	Worse	Much Worse
If you have experienced teasing how has it affected your schoolwork ?	Improved	Same	Worse	Much Worse

3b. How have your experiences of the following affected your schoolwork?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean	Not at all	A little	A lot

GETTING ON WITH FRIENDS

4a. How have the following things associated with wearing your brace affected your friendships?

For example, if you think it is easier to get on with your friends because of the way your brace has changed your smile, you would put a ring around **improved**

How have any changes in your speech affected your friendships ?	Improved	Same	Worse	Much Worse
How have any changes in your eating affected your friendships ?	Improved	Same	Worse	Much Worse
How have any changes in how you drink affected your friendships?	Improved	Same	Worse	Much Worse
How have any changes in your sleep patterns affected your friendships ?	Improved	Same	Worse	Much Worse
How have any changes in your appearance affected your friendships?	Improved	Same	Worse	Much Worse
If you have experienced teasing how has it affected your friendships ?	Improved	Same	Worse	Much Worse

4b. How have your experiences of the following affected the way in which you get on with your friends?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean	Not at all	A little	A lot

FAMILY RELATIONSHIPS

5a. How have the following things associated with wearing a brace affected how you get on with your family?

For example, if you think you argued a lot more with your parents because of your brace, you would put a ring around much worse

How have any changes in your speech affected your relationship with your family?	Improved	Same	Worse	Much Worse
How have any changes in your eating affected your relationship with your family?	Improved	Same	Worse	Much Worse
How have any changes in how you drink affected your relationship with your family?	Improved	Same	Worse	Much Worse
How have any changes in your sleep patterns affected your relationship with your family?	Improved	Same	Worse	Much Worse
How have any changes in your appearance affected your relationship with your family?	Improved	Same	Worse	Much Worse
If you have experienced teasing how has it affected your relationship with your family?	Improved	Same	Worse	Much Worse

5b. How have your experiences of the following affected your relationship with your family?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot
Dribbling	Not at all	A little	A lot
Keeping the brace clean	Not at all	A little	A lot

HOBBIES / INTERESTS

6. If you feel that wearing a brace has had any effect on your hobbies please tick the appropriate box.

For example:

If you feel that wearing a brace has meant that you get the lead roles in the school play you would tick the **I enjoy doing more** *box beside* **drama**

Activity	I enjoy doing more…….	No different	I do less…….
Music			
Sport			
Drama			
Singing			
Going to clubs eg Scouts or guides			

If you think wearing a brace has affected other hobbies or interests please write them in the activity column and say in what way by ticking the appropriate boxes.

TOOTH MOVEMENT

Now that you are wearing a brace do you feel that your teeth are moving?	Not at all	A little	A lot
Is it important to you whether or not your teeth are moving?	Not at all	A little	A lot

YOUR EXPERIENCE OF WEARING A BRACE

Is wearing a brace what you expected?	Yes	No	Not sure
Have you had any extra visits to the hospital because your brace has broken?	Yes	No	
If you have had to make extra visits because your brace has broken, has this bothered you?	Not at all	A little	A lot

YOUR ADVICE TO OTHER PATIENTS

Based upon **YOUR** experience of wearing a brace, what would **YOU** say to someone who was about to have a brace fitted?

Appendix 5: Old version of the Post-treatment Questionnaire

Treatment Questionnaire (After)

We would like to know how things have changed for you because of your treatment. Please draw a ring round **one** of the numbers on each line which is nearest to how you feel.

	No better	A little better	Much better	Very much better
It has made it easier to chew my food	**1**	**2**	**3**	**4**
It has made my family happier	**1**	**2**	**3**	**4**
It has helped me with my schoolwork	**1**	**2**	**3**	**4**
It has made my teeth look nicer	**1**	**2**	**3**	**4**
It has helped my breathing	**1**	**2**	**3**	**4**
It has made me more confident	**1**	**2**	**3**	**4**
It has helped my top and bottom teeth fit together.	**1**	**2**	**3**	**4**
It has helped me speak more clearly	**1**	**2**	**3**	**4**
It has made my face look better	**1**	**2**	**3**	**4**
It has made me feel better about myself	**1**	**2**	**3**	**4**
It has made my gums healthier	**1**	**2**	**3**	**4**
It has made me healthier	**1**	**2**	**3**	**4**
It will stop me losing teeth in the future	**1**	**2**	**3**	**4**
It is easier to make friends	**1**	**2**	**3**	**4**
It has helped to keep my jaw joints healthy	**1**	**2**	**3**	**4**
It has helped my front teeth fit together	**1**	**2**	**3**	**4**
It has made me look better	**1**	**2**	**3**	**4**
It has made me feel better about going out	**1**	**2**	**3**	**4**
It keeps my jaw joint from clicking	**1**	**2**	**3**	**4**
It has helped my back teeth fit together	**1**	**2**	**3**	**4**
It has made it easier to get on with people	**1**	**2**	**3**	**4**
It has made it easier to bite into food	**1**	**2**	**3**	**4**

If there have been any other changes because of your treatment please tell us about them on the other side of the paper.

Appendix 6: Invitation letter to experts for the first round of validation

Invitation to Participate as an Expert in a Content Validity Panel

Dear ……,
I would like to invite you to be part of an expert review panel to evaluate the content validity of three questionnaires. These questionnaires are the **Pre-treatment**, **Smiles-Better**, and **Post-treatment** questionnaires for patients who have been treated with the 0.018-inch and 0.022-inch bracket systems. They are designed to address patients' expectations, experience, and impact of fixed orthodontic appliance treatment in a randomised clinical trial to compare the effectiveness of these two systems. This study is being conducted as a partial fulfillment of the requirements for my Ph.D. degree in dentistry (Orthodontics) under the supervision of Prof. David Bearn and Dr. Grant McIntyre. Your voluntary participation in this project will provide essential information on this topic and it would be greatly appreciated. Your experience as an orthodontic professional, researcher, or educator qualifies you for participation as a member of the panel of experts to match the relevance of each item within the questionnaires to orthodontic treatment with fixed appliances.

Instructions:
Please provide your information below:
Date:
Name:
Title/Position:
Years since orthodontic qualification:

Please rate the items using the 4-point Likert scale within the questionnaires. If the item is not or only somewhat relevant to the construct under investigation then rate it as 1= not relevant or 2= somewhat relevant. If the item is relevant to the construct then rate it as 3= relevant or 4= very relevant.

The Constructs
Pre-treatment Questionnaire:
'Patient expectations of treatment with fixed orthodontic appliances'

Smiles-Better Questionnaire:
'Patient experience during active treatment with fixed orthodontic appliances'

Post-treatment Questionnaire:
'Having undergone orthodontic treatment with fixed orthodontic appliances, this will have had an impact on the patient's dental health status and lifestyle'

Please, provide your comments/ratings in the space following each question.
Thank you for your assistance.
For any further information, please contact me at: y.a.y.alnaseri@dundee.ac.uk or call XXXXXXX

Yours Sincerely,
Yassir A. Yassir
Ph.D. Student – University of Dundee

Appendix 7: Invitation letter to experts for face validation

Invitation to Participate as an Expert in a Face Validity Panel

Dear .....,
There has recently been much debate worldwide about the benefits of 0.018-inch or 0.022-inch bracket systems. As a part of my Ph.D. study, we are validating the *Pre-treatment*, *Smiles-better*, and *Post-treatment* Questionnaires for patients treated with the two bracket systems.

I would like to invite you to take part in *Content Validation* for these questionnaires, which requires an expert overview of the questionnaires to ascertain whether the content of the questionnaire is *appropriate* and *relevant* to ***Fixed Orthodontic Appliance Treatment*** by using a feedback form for reporting the outcomes.

Thanking you in advance for participating in reviewing the Questionnaires. Your opinion in feedback forms is appreciated.

Kindly find the three Questionnaires with their feedback forms. Please feel free to return by email or hard copy.

Best Regards,
Yassir A. Yassir
Ph.D. Student – University of Dundee

Appendix 8: Face validity feedback form for experts (Pre-treatment Questionnaire)

Pre-treatment Questionnaire Feedback Form	Strongly Disagree	Disagree	Agree	Strongly Agree
The content of the questionnaire is appropriate as a pre-treatment patient expectation index				
The content of the questionnaire is appropriate and relevant for orthodontic patients				
The phrases of the questionnaire are easily understood				
The questionnaire has consistent format and style				
The questionnaire covers the most important aspects of pre-treatment patient perception				
The questionnaire covers aesthetic aspects adequately				
The questionnaire covers social aspects adequately				
The questionnaire covers psychological aspects adequately				
The questionnaire covers oral health aspects adequately				
The questionnaire covers functional aspects adequately				
The questionnaire is adequate as a 'Pre-treatment Questionnaire for Orthodontic Patients'				
There are important aspects not addressed in the questionnaire. please specify below				

Do you have any other comments? please specify

Appendix 9: Face validity feedback form for experts (Smiles-Better Questionnaire)

Smiles-Better Questionnaire Feedback Form	Strongly Disagree	Disagree	Agree	Strongly Agree
The content of the questionnaire is appropriate for patient experience throughout treatment				
The questionnaire addresses changes and discomforts that happened during treatment				
The content of the questionnaire is appropriate and relevant for orthodontic patients				
The phrases of the questionnaire are easily understood				
The questionnaire has consistent format and style				
The questionnaire covers the most important aspects of patient perception throughout treatment				
The questionnaire covers aesthetic aspects adequately				
The questionnaire covers social aspects adequately				
The questionnaire covers psychological aspects adequately				
The questionnaire covers oral health aspects adequately				
The questionnaire covers functional aspects adequately				
The questionnaire is adequate as a 'Questionnaire for Orthodontic Patients during Treatment'				
There are important aspects not addressed in the questionnaire. please specify below				

Do you have any other comments? please specify

Appendix 10: Face validity feedback form for experts (Post-treatment Questionnaire)

Post-treatment Questionnaire Feedback Form	Strongly Disagree	Disagree	Agree	Strongly Agree
The content of the questionnaire is appropriate as a post-treatment patient satisfaction index				
The content of the questionnaire is appropriate and relevant for orthodontic patients				
The phrases of the questionnaire are easily understood				
The questionnaire has consistent format and style				
The questionnaire covers the most important aspects of post-treatment patient satisfaction				
The questionnaire covers aesthetic aspects adequately				
The questionnaire covers social aspects adequately				
The questionnaire covers psychological aspects adequately				
The questionnaire covers oral health aspects adequately				
The questionnaire covers functional aspects adequately				
The questionnaire is adequate as a 'Post-treatment Questionnaire for Orthodontic Patients'				
There are important aspects not addressed in the questionnaire. please specify below				

Do you have any other comments? please specify

Appendix 11: Face validity feedback form for patients (Pre-treatment Questionnaire)

Patient Number:

Face Validity for Pre-treatment Questionnaire	Strongly Disagree	Disagree	Agree	Strongly Agree
The content of this questionnaire is appropriate for patients before orthodontic treatment				
The phrases within the questionnaire are clear and are easily understood				
The questionnaire is easy to follow and is in logical order				
The questionnaire is consistent in terms of style layout and				
Some important aspects of lifestyle before orthodontic treatment are not addressed by the questionnaire. If you tick 'agree' or 'strongly agree' box, please give more details below				

Do you have any other comments? please give more details below

Appendix 12: Face validity feedback form for patients (Smiles-Better Questionnaire)

Patient Number:

Face Validity for Smiles-Better Questionnaire	Strongly Disagree	Disagree	Agree	Strongly Agree
The content of this questionnaire is appropriate for patients with braces				
The phrases within the questionnaire are clear and are easily understood				
The questionnaire is easy to follow and is in logical order				
The questionnaire is consistent in terms of style and layout				
Some important aspects of lifestyle during orthodontic treatment are not addressed by the questionnaire. If you tick 'agree' or 'strongly agree' box, please give more details below				

Do you have any other comments? please give more details below

Appendix 13: Face validity feedback form for patients (Post-treatment Questionnaire)

Patient Number:

Face Validity for Post-treatment Questionnaire	Strongly Disagree	Disagree	Agree	Strongly Agree
The content of this questionnaire is appropriate for patients after braces				
The phrases within the questionnaire are clear and are easily understood				
The questionnaire is easy to follow and is in logical order				
The questionnaire is consistent in terms of style and layout				
Some important aspects of lifestyle after orthodontic treatment are not addressed by the questionnaire. If you tick 'agree' or 'strongly agree' box, please give more details below				

Do you have any other comments? please give more details below

Appendix 14: Invitation letter to experts for the second round of validation

Invitation to Participate as an Expert in a Content Validity Panel

Dear …….,
I would like to invite you to be part of an expert review panel in the second phase of the content validity evaluation of three questionnaires. These questionnaires are the **Pre-treatment**, **Smiles-Better**, and **Post-treatment** questionnaires for patients who have been treated with the 0.018-inch and 0.022-inch bracket systems. They are designed to address patients' expectations, experience, and impact of fixed orthodontic appliance treatment in a randomised clinical trial to compare the effectiveness of these two systems. This study is being conducted as a partial fulfillment of the requirements for my Ph.D. degree in dentistry (Orthodontics) under the supervision of Prof. David Bearn and Dr. Grant McIntyre. Your voluntary participation in this project will provide essential information on this topic and it would be greatly appreciated. Your experience as an orthodontic professional, researcher, or educator qualifies you for participation as a member of the panel of experts to match the relevance of each item within the questionnaires to orthodontic treatment with fixed appliances.

Please rate the items in each questionnaire to the underlying construct and its domains using the 4-point Likert scale within the questionnaires. If the item is not or only somewhat relevant to the construct under investigation then rate it as 1= not relevant or 2= somewhat relevant. If the item is relevant to the construct then rate it as 3= relevant or 4= very relevant.

The Constructs
Pre-treatment Questionnaire:
'Patient expectations of treatment with fixed orthodontic appliances'

Smiles-Better Questionnaire:
'Patient experience during active treatment with fixed orthodontic appliances'

Post-treatment Questionnaire:
'Having undergone orthodontic treatment with fixed orthodontic appliances, this will have had an impact on the patient's dental health status and lifestyle'

The following domains should also be considered:

- Relevance for orthodontic patients
- Patient perception/experience with orthodontic treatment
- Aesthetic aspects of orthodontic treatment
- Social aspects of orthodontic treatment
- Psychological aspects of orthodontic treatment
- Oral health aspects of orthodontic treatment
- Functional aspects of orthodontic treatment

Please, provide your comments/ratings in the space following each question.
Thank you for your assistance.
For any further information, please contact me at: y.a.y.alnaseri@dundee.ac.uk or call XXXXXXX

Yours Sincerely,
Yassir A. Yassir
Ph.D. Student – University of Dundee

Appendix 15: New version of the Pre-treatment Questionnaire

Treatment Questionnaire (Before)

These are some of the reasons why people request orthodontic treatment with braces. Please draw a ring round **one** of the numbers on each line.

	Not a reason			**Very much a reason**
To make my teeth look better	1	2	3	4
To make my smile better	1	2	3	4
To make my face look better	1	2	3	4
To make me more confident and feel better about myself	1	2	3	4
To make me feel better about going out and easier to get on with people	1	2	3	4
To help my top and bottom teeth fit together	1	2	3	4
To help my front teeth fit together	1	2	3	4
To help my back teeth fit together	1	2	3	4
To help me chew food more easily	1	2	3	4
To make it easier to brush my teeth	1	2	3	4

If you have any other reasons to undergo orthodontic treatment with braces, please write these below

Appendix 16: New version of the Orthodontic Experience Questionnaire

6 months from start of treatment

Orthodontic Experience Questionnaire

A Few Questions about You and Your Brace

We would like to know how you feel about wearing your brace. By answering these questions, YOU can help to make wearing a brace better for people in the future.
Please **circle** the answer, which is nearest to how you feel.
*Please tell us about how you feel **NOW**, not about when your brace was new.*

Your experience of wearing a brace

Is wearing a brace what you expected?	No	Not sure	Yes
Have you had any extra appointments because your brace has broken?	No		Yes
If you have had to make extra appointments because your brace has broken, has this bothered you?	Not at all	A little	A lot
Now that you are wearing a brace, do you feel that your teeth are moving?	Not at all	A little	A lot
Having to keep the brace clean is a nuisance	Not at all	A little	A lot

How have the following things changed due to wearing your brace?

Eating	Improved	No change	Worse
Appearance	Improved	No change	Worse
If you were called names or bullied about your teeth before you started treatment, has this changed?	Less	No change	More

How have the following affected you?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Soreness from rubbing	Not at all	A little	A lot
Feeling embarrassed	Not at all	A little	A lot

We would like to know if wearing a brace can affect other things in your life

SCHOOL OR WORK

How have your experiences of the following affected your schoolwork/work life?

Sore teeth	Not at all	A little	A lot
Soreness in your mouth	Not at all	A little	A lot
Being called names or bullied due to your brace	Improved	No change	Worse

GETTING ON WITH FRIENDS AND FAMILY

How have the following changed your interaction with friends and family?

Changes in your appearance	Improved	No change	Worse
Being called names or bullied due to your brace	Improved	No change	Worse

HOBBIES / INTERESTS

We would like to know if wearing a brace has had any effect on your activities. Please list your hobbies/interests and circle the appropriate box

e.g. Music	I enjoy doing more…….	No different	I do less…….
	I enjoy doing more…….	No different	I do less…….
	I enjoy doing more…….	No different	I do less…….
	I enjoy doing more…….	No different	I do less…….

YOUR ADVICE TO OTHER PATIENTS

Based upon **YOUR** experience of wearing a brace, what would **YOU** say to someone who was about to have a brace fitted?

Appendix 17: New version of the Post-treatment Questionnaire

Treatment Questionnaire (After)

We would like to know what has changed because of your orthodontic treatment. Please draw a ring round **one** of the numbers on each line nearest to how you feel.

	No better	A little better	Much better	Very much better
It has made my teeth look better	1	2	3	4
It has made my smile better	1	2	3	4
It has made my face look better	1	2	3	4
It has made me more confident and I feel better about myself	1	2	3	4
It has made me feel better about going out and easier to get on with people	1	2	3	4
It has helped my top and bottom teeth fit together	1	2	3	4
It has helped my front teeth fit together	1	2	3	4
It has helped my back teeth fit together	1	2	3	4
It has made it easier to chew my food	1	2	3	4
It is easier to brush my teeth	1	2	3	4

If there have been any other changes because of your treatment, please write these below.

Appendix 18: The invitation letter and email sent via BOS to the participants

Dear BOS Member,
There has recently been much debate worldwide about the benefits of 018 or 022 bracket systems. As a part of my Ph.D. study, I would like to invite you to take part in a survey to discover current appliance use in the UK. This an important part of reporting an RCT comparing the effectiveness of treatment between the two bracket slot sizes and will be combined with international data for comparison.
Please follow the link below to complete the short anonymous survey which will take **less than 5 minutes** of your time to complete.
https://www.surveymonkey.com/s/LB36M2Q

Thanking you in advance.
Best Regards,

Yassir A. Yassir
Ph.D. Student – University of Dundee

The Audit Committee of the Clinical Governance Directorate has approved this audit for circulation.
British Orthodontic Society (registered charity 1073464) 12 Bridewell Place, London EC4V 6AP

Appendix 19: Responses to the open-ended question to determine the reason for using bracket slot

Other (please specify)	Category
I was trained with an 022 system so have used it ever since	Taught and Trained
I trained with this system	Taught and Trained
Have always used this slot size. It works well in my hands. Have never considered any reasons for changing slot size.	Taught and Trained
What I trained with	Taught and Trained
This is what I was trained on. I havent used 0.018	Taught and Trained
Trained using this prescription	Taught and Trained
Have always used 0.022 slot brackets	Taught and Trained
Taught to use it at University (familiarity)	Taught and Trained
Trained in this	Taught and Trained
No experience of 0.018 systems	Taught and Trained
What I was trained on	Taught and Trained
If I'm honest....habit	Taught and Trained
Slot system I trained with.	Taught and Trained
System I trained with	Taught and Trained
Familiarity	Taught and Trained
Appliance system I was trained with - I have never used an 0.018 slot system	Taught and Trained
I was taught with an 0.022 system so have continued to use that since	Taught and Trained
Combination of training, familiarity and better outcomes	Taught and Trained
trained on this system	Taught and Trained
Experience, was brought up on 0.018 slot preasjusted edgewise is an 022 slot	Taught and Trained
Habit	Taught and Trained
What I was taught to use & what is available in hospital	Taught and Trained
Was trained to use 0.022, never changed	Taught and Trained
Trained with it from start career	Taught and Trained
What I was trained on and I'm used to using	Taught and Trained
Always have done, evidence????	Taught and Trained

Other (please specify)	Category
the size my peers used when I was training	Taught and Trained
This was used during my training - never used 0.018"	Taught and Trained
I was trained in 022 system	Taught and Trained
Always have done	Taught and Trained
Never used an 0.018 slot	Taught and Trained
What I was trained	Taught and Trained
always have	Taught and Trained
Have always used 0.022	Taught and Trained
That's what I was taught with.	Taught and Trained
Trained with it	Taught and Trained
Most widely used in UK and trained on this and suits my purpose in years after training.	Taught and Trained
Have never actually tried 018. trained on 022.	Taught and Trained
What I was brought up with	Taught and Trained
Trained to use this system	Taught and Trained
Trained with system.	Taught and Trained
Convention, never used 018	Taught and Trained
Trained with this slot size & practice i work in uses this	Taught and Trained
Familiarity from training, in addition to better outcomes	Taught and Trained
Always used it, never used 018, just assume 022 is better	Taught and Trained
Taught with this system.	Taught and Trained
Always have done!	Taught and Trained
Training was based on that slot size	Taught and Trained
Trained with this system	Taught and Trained
Trained mainly on this bracket slot dimension	Taught and Trained
Familiary with use	Taught and Trained
All above, plus what I am used to !	Taught and Trained
I was tarined with this slot size!	Taught and Trained
Taught it and saw no reason to change	Taught and Trained
Was trained with brackets of that size. All my colleagues use this bracket slot size.	Taught and Trained
Better rotational control	Better Control
Thicker wire gives greater archfom control in all planes of space especially in orthognathic cases, together with greater rigidity for 'sliding mechanics. Also greater 'slop' control and variation in stainless steel and flexible wires	Better Control
Best of a bad lot	Better Control
Stronger wire in surgical cases	Better Control
Ease and flexibility of use in initial stages	Better Control
I've always used it and believe I get a better overbite reduction	Better Control
Easier to use. Stronger wires for overbite control.	Better Control
Allows lower forces with lighter wires	Better Control
Ability to use sliding mechanics	Better Control
Initiallly lighter forces to begin tooth movment. Final archwires are dimensionally more stable to achieve torque control	Better Control
Easier engagement in initial wires	Better Control
Bigger range of potential wire sizes. This gives several spin-off biomechanics advantages e.g. lighter early forces and stiffer later wires	Better Control
Its what i've always used since my MOrth training. Better wire size options than 018	Better Control
Quality bracket/archwire system, excellent results	Better Control
Prefer design of 0.022 MBT brackets as easy to use (attahc modules, auxiliaries etc) - slot size is not important to me but bracket design is	Better Control
Never used .018. Would be concerned about lack of control with less rigid wires	Better Control
I used 018 and 022 in different units as a postgrad. The 018 system required a lot of auxiliary arches. I find the 022 slot a good basis as I dinf th ea/w choice for 018 too limiting but still use some of the 018 mechanics.	Better Control

Other (please specify)	Category
Higher dimension working archwires felt to be better for sliding mechanics.	Better Control
Can use thicker archwire do less tipping. More universal that 018	Better Control
We were always told better at overbite and torque control but there has never been an RCT?	Better Control
Easy to add auxiliaries such as piggy backs	Better Control
Greater range of wires; easier sliding	Better Control
Having a wider slot allows the use of a wider range of wires and a such gives the operator better control.	Better Control
I use 0.018 slot for short cases- cosmetic and 0.022 for comprehensive I find rectangular wires for 0.018 slot are not suitable for space closure and torque and prone to fracture/bending	Better Control
Ability to use twin wire techniques. Ability to increased dimension wires for overbite control.	Better Control
Better overbite reduction, arch dimension control, lateral control, more expansion effect	Better Control
More forgiving	Better Control
Just what's available in the departments I have ever worked in	No Choice
Available in dept	No Choice
thats what the department buy!	No Choice
Available since introduction of SWA in the clinic.	No Choice
Always used this and this is what we have at work	No Choice
Practice uses this when joined	No Choice
readily available	No Choice
damon is only 022	No Choice
Bracket designated by the practice principal	No Choice
In general use	No Choice
For question 7 does Tip-edge count as a conventional bracket? If so I use 100% conventional.	No Specific Reason
No preference regarding slot size	No Specific Reason
Awaiting proof that one is better than the other!	No Specific Reason
No choice	No Specific Reason
No reason	No Specific Reason

Appendix 20: List of publications/presentations from the study

1. **Yassir AY, McIntyre GT, Bearn DR (2017).** Three questionnaires to assess the perception of fixed orthodontic therapy before, during and after treatment: validity and reliability. European Journal of Orthodontics, 39 (4), 402-410. https://doi.org/10.1093/ejo/cjw076.
2. **Yassir AY, Bearn DR, McIntyre GT (2017).** Audit comparing the BOS fixed appliances PIL with actual patient experience during treatment: Local clinical audit. Clinical Effectiveness Bulletin, 40-42.
3. **Yassir AY, Bearn DR, McIntyre GT.** Variation in bracket slot sizes and prescriptions used by specialist orthodontists in the United Kingdom. [Poster presentation in the European Orthodontic Conference, Stockholm-Sweeden, 2016]
4. **Yassir AY, Bearn DR, McIntyre GT.** Evaluation of experience of orthodontic patients during treatment: Local Audit. [Poster presentation in the British Orthodontic Conference, Brighton-UK, 2016]
5. **Yassir YA, El-Angbawi AM, McIntyre GT, Bearn DR.** The 0.018-inch or 0.022-inch slot bracket system? [Oral presentation in the European Orthodontic Conference, Montreux-Switzerland, 2017]
6. **Yassir YA, McIntyre GT, El-Angbawi AM, Bearn DR.** Comparison of anchorage loss between the 0.018-inch and 0.022-inch slot bracket systems. [Poster presentation in the European Orthodontic Conference, Montreux-Switzerland, 2017]